Governance Workgroup Public Hearing
Draft Transcript
October 4, 2010

Presentation

Judy Sparrow – Office of the National Coordinator – Executive Director
Good morning, everybody and welcome to the HIT Policy Committee's Governance Workgroup. This is the Federal Advisory Committee, so there will be opportunity at the close of the meeting for the public to make comment. We will post a transcript on the ONC Website. Just a reminder for workgroup members to please identify yourselves when speaking for attribution. We'll go around the table here and just introduce those members who are sitting in Washington D.C.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
This is John Lumpkin from the Robert Wood Johnson Foundation.

Mary Jo Deering – ONC – Senior Policy Advisor
Mary Jo Deering, ONC.

Leslie Harris – Center for Democracy & Technology – President & CEO
Leslie Harris, Center for Democracy and Technology.

Lisa Tiderow – MITRE Corporation
Lisa Tiderow

Mariann Yeager – NHIN – Policy and Governance Lead
Marian Yeager, contractor to ONC and Staff Support.

Judy Sparrow – Office of the National Coordinator – Executive Director
We do have a number of workgroup members on the telephone. Christine Bechtel is on her way in, so let me just do a quick roll call. John Glaser? John Mattison? Girish Kumar? Linda Fischetti? Michael Matthews?

Michael Matthews – MedVirginia – CEO
I'm here.

Judy Sparrow – Office of the National Coordinator – Executive Director
John Houston?

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security
Here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Carol Diamond? Wes Rishel?

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Tim O'Reilly? With that, I'll turn it over to Dr. Lumpkin.

Laura Adams – Rhode Island Quality Institute – President & CEO
This is Laura Adams. I'm on as well.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Good morning, long time no see, actually, all of about six days. I'd like to welcome you to our first meeting of the committee as a whole. Today we have the task of going through a few documents that have been prepared by the subgroup. I'd like to thank Michael and Carol and John for helping pull that together, as well as Mary Jo and Mariann for helping us get to this point.

I'd like to remind you again of some of the timelines, that is, on October 20th we will be presenting to the Policy Committee our preliminary findings. The final findings will be on November 19th. We are geared towards trying to make recommendations for the Office of the National Coordinator on the issue of governance for the Nationwide Health Information Network (the NHIN) with an asterisk of course that that is in the process of being changed.

We are going to today do a couple of things. We're going to start off with a review of the meeting that we had last week, the hearing on governance where we had invited speakers and four panels. We'll follow up with a discussion of initial recommendations, the scope documents, which was provided by the Office of the National Coordinator. It's a two page document that was part of your e-mail package that you got on Saturday.

The second part of the discussion will be a discussion on basic principles that will be included and hopefully we'll be able to get to that in the first portion of our meeting this morning. Followed by that, we will then go into a slightly longer document that's entitled "Policy Committee Governance Workgroup Governance Gap and Needs Assessment." We believe that this document will position us to present the areas that we believe that are important for us to be able to share with the Policy Committee. Subsequent to that meeting, verification of the areas for which governance should be considered, we will then make a recommendation for the November 19th meeting that will talk more about who should do those components of governance.

So that's our agenda and our objectives for the meeting today and then also a reminder of our timeline. Are there any questions?

Laura Adams – Rhode Island Quality Institute – President & CEO
Are we expecting the entire committee to be at the dates where we're making presentations of our work? I just want to be sure for calendaring purposes if we're expected to be in Washington for those dates.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
I think everyone is invited to come, but I think I'm the only one who needs to be there and Mary Jo and Mariann and the rest of the crew.

Laura Adams – Rhode Island Quality Institute – President & CEO
Thank you.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Any other questions or comments before we go on? At this point let's take a few minutes and review what we thought we heard at the governance workgroup hearing that was on September 28th. I'm going to go through this. I believe everyone on the workgroup has a copy of these slides, so as I go through feel free to enhance any of the slides which I'm going through rather than waiting until the end.

The key things that we heard, first, is that the focus should be governance of governances. In other words, build upon existing authorities and that the significant value that would be added is through coordination. Leverage the lessons that have already been learned by the various exchanges as well as the DURSA document that has been part of the NHIN governance to establish a simple set of core rules to govern the complex environment. Any additional comments and thoughts people had on just the general themes?

Michael Matthews – MedVirginia – CEO

I do have a comment on the slide deck. I think I must have failed in my articulation of what I consider the importance of the governance activity, the history, the foundation and infrastructure over the exchange towards the end of the day. I don't see reflected anywhere in the slide deck the specific reference to the coordinating committee, to the exchange, to the mechanisms that are in place. I see generic references to it leveraging existing authority, but I'm just going to continue to ... on the point that we're not starting from scratch, that the exchange has a three year history of building governance mechanisms. To not explicitly acknowledge and build upon that I think we're being remiss and it's an unnecessary step back in our entire process, so I'd like to hear from the group whether there's any opposition to that inclusion or whether this is some sort of omission not by intention.

Mary Jo Deering – ONC – Senior Policy Advisor
Let me take the first stab at that, because it was certainly not at all intentional. In fact in this higher level language that you see scattered across these places, it was absolutely intended to convey exactly what you've said. I do think that if the group would like us to be more explicit in showing that in the summary, we certainly can. But I can certainly say as someone who put these slides together that the intent was to have captured what you said without naming it. We didn't name anything specifically throughout these slides, they're really themes rather than specifics, so my apologies.

Michael Matthews – MedVirginia – CEO
There's no need to apologize, Mary Jo. I just wanted to again say that with all the hard work, with yourself included in the middle of all that hard work over the past three years, I'd rather be more explicit than implicit about all of that. I think that the public interest will be represented. I think the public will be supportive knowing that we have ... our work over the past three years.

A point made, not at the hearing but in the meeting prior to that is just the distinction between the exchange and the work that's been done there regarding governance and what needs to be done versus everything else." The everything else," to me the starting point is still what is in the everything else" bucket and then from that we would drive toward what the governance authority or authorities are over that. So that continues to be my ... framework around the many issues that are before the body and again I think it might serve us well as we get through it. So, enough on that, John, as we proceed through the rest of the summary. Thank you.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
So please be vigilant as we go through various iterations of the preliminary report. I think that we want to indicate that this is something that is building upon the shoulders of giants and that we specifically name what those things are as part of some of the introductory materials.

W
When you say we're building on the current NHIN exchange, are we saying that governance body is now just going to be expanded, or are we talking about the rebuilding of the—

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Experience, lessons learned—

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
First of all, I agree entirely with Michael in terms of not only the work that's put into the current governance but the effectiveness. I want to be sure, though, that we, at some point, explicitly state the differences in scope between the current experience and the anticipated requirement. So while we've been dealing with a dozen or so entities now have we stated a target, can we state a target for the number of entities that we would be approaching with this governance? Because often the structures that are necessary for an order of magnitude increase in the number of entities are different than for a small group.

In addition, I'm confused about the slides that you're using right now. I didn't see them in the material that was sent out. Is there a Website I can go to to pull them down?

W
Wes, they were in the packet. Do other people have them? It was sent Saturday morning.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
No, I looked there.

M
Yes. They were included in my e-mail.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Okay, then I'm just confused. I'll figure it out. Thank you.

Judy Sparrow – Office of the National Coordinator – Executive Director
Wes, they're on the ONC Website, though.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
I am pretty much covering all the parts, so while you're downloading that you can keep up.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Yes, so I'm looking for a PowerPoint, is that right?

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
That's correct. I think it's entitled Governance Hearing."

Michael Matthews – MedVirginia – CEO
If I can weigh in one more time, please, I definitely agree with Wes' point about the number of parties that are to be governed. But I want to make sure to the question, I'm not sure who asked it before, are we talking about expansion of the exchange or the governance authority over the exchange. That is not where I'm coming from at all. It's acknowledging that the exchange is in place with some governance mechanisms in place that we can either leverage or at least take the lessons learned from it. So I was not in any way advocating expansion of the coordinating committee or the exchange itself.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Any other comments on the first slide? Moving on to the second slide then, one of the key themes was that consumer privacy protections are inherent components of governance. That's been consistent with the conversations we had in our first conference call, that we needed to look at established general obligations to protect information at a national level for all entities that are involved in exchange, that governance needs to address patient consent and use of data based upon that consent. In addition, some additional requirements for privacy and security above and beyond existing law are expected.

Then finally, that some states and implementers request that the models for uniform patient consent, it was noted in some of the materials we got from the two exchanges when we asked for subsequent information, patient consent was one of the issues they raised, and help with processes to harmonize conflicting levels of consent under state laws. Given that we're not looking at legislation that would supersede or preempt state laws, so we need to recognize that there will be some differences based upon state by state legislative regulatory structure.

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security
A question about the notion of uniform patient consent, implicit to that is the idea that there's an opt in or an opt out. Should I read into that the idea that there's an opt in, or am I reading too much into that?

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
I think that that would be reading too much into that. I think it was more of, as we get into this discussion that there's going to be some that will be done by agreement and some which would have a more rigid structure. My interpretation of the comments was they were looking for models as opposed to imposition of a uniform patient consent.

Leslie Harris – Center for Democracy & Technology – President & CEO
Going back to the second bullet, ~~should~~ address patient consent and data use." Are we talking about generally components of governance, or the component of governance of governance? Because we've got states making decisions all over the place on the consent question, so I'm a little confused. Obviously these are elements of governance, but I can't figure out if they're elements of governance we're supposed to be conceptualizing at this sort of coordinating governance of governance level.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
I will give it a try and then others can chime in. The critical issue for exchange to occur, particularly when one thinks about going from Paducah, Kentucky to Eureka, California is an understanding that when I share my data that there is a consent that was given by my patient that when that patient shows up in Eureka, that they're going to have the same expectation from when I first collected that data.

Leslie Harris – Center for Democracy & Technology – President & CEO
... obligation model. Essentially we're talking about having to get the consent, whatever it is, out of the states to travel with it as—

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
No.

Leslie Harris – Center for Democracy & Technology – President & CEO
No?

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
It's an issue of how do you build a trust structure.

Leslie Harris – Center for Democracy & Technology – President & CEO
I understand that, but what I'm trying to understand is, is this based on an assumption that state HIEs have rules and models for inside the state what the rules are based on their laws for data exchange in terms of consent. Then there will be a uniform view of that for between the states and between these big entities.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
I think you're jumping a couple of steps ahead of us because what we're trying to do is to look at the areas for which we believe that governance decisions need to be made and then we will, for our report on the 19th of November then actually have a decision on what that ought to be.

Mary Jo Deering – ONC – Senior Policy Advisor
This is a good time to remind people that we are working very closely with privacy and security Tiger team which has this squarely on their plate, and they are delivering some recommendations that we will be synching up with. One of the reasons Lisa Tiderow of MITRE Corporation is with us is so that in real time she is synthesizing what we say in light of what she knows is the agenda for the Tiger team, and John will have a first meeting with the Tiger team the day after tomorrow. So it's premature for us to think necessarily what we have to do, but we can count on getting that input from the Tiger team as they go along.

John Mattison – Kaiser Permanente – Chief Medical Information Officer
Good morning. This is John Mattison. I joined.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Good morning, and welcome. Any other comments on this slide? Then we'll move to the next one. Another key theme is that the federal government plays an important role in overall coordination, that states and implementers express interest in maintaining some level of autonomy in overseeing their exchange, but did look to the federal governments to do a couple of things.

The first is to provide templates, tools and resources to facilitate development of common standards, promote interoperability and security of health information, to build a network of trust of not only will the data be protected, but also that it will have the same semantic meaning as it moves from one location to another, to create a framework for interoperability among exchange entities and to coordinate dispute resolution process amongst those entities. Finally, that the federal participation is an indicator of trust. In other words, that it essentially has from the federal brand on this process which gives it its imprimatur. Any comments on this slide?

Moving on, that common standards are needed to ensure interoperability and establish trust and security of the information. The first, that the federal government should serve in a coordination role to establish standards, specifications and criteria for adoption and utilization. I want to emphasize the word coordination role on that. The general agreement views industry standards that are available, which has been a consistent part of developing our nascent health information exchange network. Stakeholder participation in the standards development process is a key ensuring adoption, which has been also a critical component of the standard development process. Standards for ensuring security of health information should be included. For them it's a dichotomy between security and privacy, which we're going to have to tease out a little bit, hopefully with some help from the Tiger team. Any comments on this slide?

Then the next thing that we heard, the next slide, is validation mechanisms are needed to ensure adherence and compliance with established standards. We're going to need a little work on this. They may include certification and testing and/or accreditation. The tricky part on that is that we're dealing with a field that's in evolution and so it may be a bit of a challenge but I think that one of the components is how do you know if somebody is fully capable of playing based upon our concept of trust. There needs to be some sort of verification of that.

Second, that some implementers advocated nationwide certification of systems and networks. That's not a recommendation. That's an observation from the hearing. Others advocated for a national coordination of accreditation or a national level accreditation program. So these were other themes that we heard at the hearing.
Any comments there?

Compliance enforcement mechanisms are essential components of a governance framework. Contracts are a common vehicle for ensuring compliance. They can include conditions for termination from participation. In other words, for purposes of patient safety, privacy, or security concerns. Auditing is often performed in other industries and that auditing structure varies from industry to industry. Enforcement models vary, but there's a role for federal government, particularly on obvious and substantive infractions, and that liability should be linked or has been linked in other governance structures to measurable damage. We had a fair bit of discussion about this, and comparing and contrasting damage in the financial system versus the health information. Comments on this?

Michael Matthews – MedVirginia – CEO
Feel free to put me on mute at any point. I think a reference specifically to DURSA on this page would be appropriate. These are incorporated in there and again not to say that DURSA's the be-all and end-all for all things NHIN, but where that is in place I would suggest that it be specifically referenced. Thanks.

John Mattison – Kaiser Permanente – Chief Medical Information Officer
Just to piggyback on Michael's comment, I think the language around that could even go further to the extent that use the DURSA and adapt it to the extent that it is applicable.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
So perhaps as we're thinking through what we heard, because we do hear a presentation on DURSA, is perhaps a bullet point specifically under the first one that DURSA's an example of that. Other comments?

Leslie Harris – Center for Democracy & Technology – President & CEO
May I just ask a question on liability—?

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Sure, go ahead.

Leslie Harris – Center for Democracy & Technology – President & CEO
... measurable damage, because—

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
I'm going to sort of suggest since we're sitting here we may forget to do this, but start off with your name.

Leslie Harris – Center for Democracy & Technology – President & CEO
I assume this came from financial services and eCommerce and where this is a big fight going on about whether you have to ... measurable harm. That may be appropriate in some context, but I would be really cautious here that we're dealing with health data. I want to go back to our slide about the ... standard and data breach.

Mary Jo Deering – ONC – Senior Policy Advisor
I think what people found intriguing is that recognizing the vast differences in the two fields, people wondered whether the real principle that he made was that actually it's misaligned eCommerce area, in that those, since the liability resides at a higher level but often the breaches occur down at the merchant level but they have no liability, it just so happens that in most cases the liability is bumped upward and so there's misalignment. So it's just to see whether there is any way to look at aligning those—it's not just from a punishment point of view, it's that then they have no incentive to make the corrections and the innovations that could actually improve the security.

Leslie Harris – Center for Democracy & Technology – President & CEO
Right, and I agree with that and I agree with—

John Mattison – Kaiser Permanente – Chief Medical Information Officer
The way we see it in the testimony is that in order to achieve a self-correcting system the financial and punitive liability should be aligned with the source of the breach or problem associated with that liability.

Leslie Harris – Center for Democracy & Technology – President & CEO
I agree with that as well, so maybe I don't disagree with this, maybe it's just how it's stated.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Further discussion on the themes from what we heard in the hearing? Okay, last slide. That governance should be structured in a way to be adaptable for the future, recognizing that the industry is evolving significantly, so governance must be evolutionary and scalable, back to the earlier comments of I think it was Wes who commented on the difference in scale between the current health information network versus what we may expect the exchange to look like in the future. It must support and encourage innovation and that follows up in a discussion that we had before about enforcement, which is that the liabilities and structure of that should be designed in such a way to encourage innovation and those who would be the innovators would be part of that governance and adherence structure. Avoid rigid rule making, and instead develop a broad framework that is adaptable to changes in the industry. That goes into the component related to cooperation that we've had some conversation about and it should have an evaluation and learning aspect to gather insights and adjust and learn from experiences.

So those are a summary of what we heard at the hearing. Are there additional comments that members may want to make? Okay, thank you. We're going to move to the next item on the agenda, which are the initial recommendation scope and principles, and Mary Jo is going to tell us about the document that we got from ONC.

Mary Jo Deering – ONC – Senior Policy Advisor
So you got a document which I believe is up on the Website now that's labeled ̶ Governance for a Nationwide Health Information Network Discussion Document." This is really not a direct action item for

the workgroup per se, but it's a response—that's the wrong document, by the way. There we go. This is in response to a request from the small group and the workgroup to better understand how ONC was beginning to think about governance and were there any sort of guardrails or guidelines or framework. So we put together this very short, rather high level document to say what our working assumptions are, and that governance should focus on elements of trust and interoperability with compliance of these elements to meet the goal.

Clearly a theme which has emerged not only within ONC but already in the small group is that trust and interoperability are two pillars on which governance is going to stand. There's an assumption that all parties of information exchange will be subject to applicable law, some may not be HIPAA covered entities, however; that certification of technical solutions used for exchange or accreditation of entities that facilitate exchange, whether they, and there's different acronyms and words to describe all of these, but we meant to be absolutely inclusive in this, that any kind of entity that facilitates exchange might be subject to some kind of accreditation and there's an assumption that there will be a component of governance that does have this element in it; that the forms of governance and any baseline rules should follow the functions or services requiring governance; that, and here you're already hearing echoes from the hearing, that our rule making process should establish minimum rules and be flexible to allow for the market to develop and innovate.

Believe me Steve Posnack is sitting down to the left of me, and Steve really is Mr. Rule Writer in ONC and believe me he does not want to have to go back and write new rules every six months to adapt to changing conditions. So we certainly recognize the need to be flexible. Again, build on existing authorities, and this certainly recognizes the rule of states, it recognizes the rule of, say, OCR in overseeing HIPAA, it recognizes the FTC and what it does in the online privacy world, etc., and again it also though implies recognize what's working to the extent that it's working.

So what is the potential scope of the governance rule? Well, we really intend to specify the rules, structures, and/or processes through which trust and interoperability elements should be governed, established, maintained, validated, overseen and enforced. So that's a pretty succinct statement .... The potential levers that are available to promote participation in these would include that entities who want to be recognized or use a brand which is going to be determined, could be encouraged to do so.

Clearly there are entities who wish to receive federal funds or who do receive federal government funds, and levers exist there, and entities who wish to receive federal health information. Let me only make a couple of observations about the second two there, is that one of the things about rule making is that we can only go so far within our writing of this rule to accomplish some of the goals that may need to be accomplished. So some of the levers may have to be accomplished outside of this particular rule itself, but not necessarily outside of what you might consider a broader governance structure. Entities may demonstrate compliance with a set of trust and interoperability criteria based on the exchange functions that they either provide or they're seeking to use. Then the next bullet is really important and it's a reflection of input to date already from the privacy and security Tiger team, which is that clearly it's the sensitivity and the degree of their access to sensitive information which has to be part of the sliding scale against which you build the governance function. So we certainly recognize that. Next page, please.

Again, there are various ways to consider compliance and enforcement, and again these are just considerations. We look forward to the workgroup's input on this. There certainly can be direct oversight by HHS in some areas, accreditation certification we said we assume will emerge as part of the recommendations and certainly part of the rule. There could be required compliance reviews, maybe you've named outside entities. Self-assessment and representation are used successfully in some areas for some purposes. There's the right to exclude someone from participation in the network," again, here assigning risk and liability to those in the best position to not only manage risk but to innovate to improve security at the same time as well, and of course there's private contracts which exist. So we're pretty crisp in what we're really looking forward to receiving from you. We would like to know what are the functions and activities and services that require governance and what are the minimum elements within each of those. And that is basically the work of your first phase. That's what you're going to be chewing on a lot today and working toward to present to the policy committee on the 20th.

Then the next bullets are a little bit more of phase two, so who should specify the policy. Is it the federal government? Does somebody else develop some of the policies? How and/or by whom should those elements be governed? What are the oversight enforcement or accountability approaches that should be applied both to the participants, and again based on the functions that they provide and whether they are voluntarily complying or are required to comply. So that in a nutshell, and at a high level, is how we're thinking of it and what we're looking forward to.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Just to clarify what our task is with this document, it's not our charge to refine this document. This is ONC saying what they think we should do. However, as a ... committee if we believe that there are areas that are beyond the scope that we ought to comment on, we have the right to do so. So are there any questions or comments about the scope document from the ONC?

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security
With regard to those last five bullet points that Mary Jo just described, I think the second bullet point seems to be incredibly limiting, and I'm just wondering whether it really is intended to be identified, the minimum elements that relates to the activities, services, and functions identified in the first bullet.

Mary Jo Deering – ONC – Senior Policy Advisor
I'm not sure I understand your question.

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security
The bullet says identification of minimum elements for trust and interoperability for each function. Trust and interoperability seems to be very limiting and I think that the concept of minimum elements is a broader exercise, in my mind, and applies more generally to the functions, activities and services that require governance, I guess is my point.

Mary Jo Deering – ONC – Senior Policy Advisor
I think you're absolutely right, and I'll certainly allow others from ONC to jump in here. I think the second bullet is possibly we were trying to be so high level, and as I've mentioned before, we have generally recognized trust and interoperability as broad buckets. So I don't think we are interpreting them narrowly, it's just as a good shorthand way for these two real major components of governance. So did you have a suggestion that you would like that could clarify for me what you think you're not seeing in bullet two?

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
I think trust and interoperability are objectives from governance and services and functions are assumptions by which you achieve those objectives. So I just want to make sure we're not mixing apples and oranges.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Right.

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security
Maybe the way to reword this then is to say identification of minimum elements for functions, activities, services that require governance in order to achieve trust and interoperability for each function."

Mary Jo Deering – ONC – Senior Policy Advisor
Excellent. Thank you.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
I have a little bit broader question so you may decide it's out of order. I'm looking at this and I'm trying to figure out where responsibility for success or accountability for success comes together with governance. In a world with a structure of less complicated governance than this one we would be looking to find an organization or person and say you are jointly responsible for the success of this endeavor, including those things that make it more successful and those things that are necessary to keep it from going off

the rails. I look at various elements here such as the possibility of certification of entities and things like that and I'm just trying to get a handle for how much the governors here are measured by the success of the entity versus the failure to go off the rails.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
I think you ask a very pertinent question. As I remember from my training very early on in medical school or residence the phrase that was used often was to defuse responsibility is to defuse blame." I think in the environment in which we're in right now you've got the national coordinator who's basically responsible for the success of the system. Our job, as I see it on the workgroup, is to try a comfortable space between saying you're ultimately responsible, therefore you have ultimate authority over everything, and you're responsible and you have no authority or guidance of the system at all. Somewhere in between lies the truth that we're trying to get to. I think your point needs to remind us at the end of the day that if I were sitting in the chair of the national coordinator looking at the recommendations from this committee, there would need to be some level of comfort that those who are in the position of making governance decisions and looking at how the system runs have clear not only authority but responsibility.

John Mattison – Kaiser Permanente – Chief Medical Information Officer
I agree with everything you just said, John, and with Wes as well. I might add a different way of addressing Wes' question in addition, and that is to ensure that the governance structure (s) themselves are constituted predominantly by the participants in the exchange. That in and of itself will help realign the process with success because the participants have a vested interest in success, and ONC clearly has a key role in this; the participants themselves absolutely depend upon success.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Other comments? Okay, Christine.

Christine Bechtel – National Partnership for Women & Families – VP
The page before this I think did include some references to the kind of structure that might serve in a governance role, but I don't really see it in these five bullets here. One of the things that I think we heard from the panel that included NQF was around the need for multi-stakeholder representation, and particularly consumers, obviously near and dear to my heart, in the governance body and all system transparency and therefore trust in the way that that body makes decisions. So I just want to make sure that that's in scope for us.

Mary Jo Deering – ONC – Senior Policy Advisor
I only want to add that if nothing else that would be a perfect segue to the principles discussion, because that's exactly where that's going to be discussed. But I don't want to cut off discussion of scope yet.

Christine Bechtel – National Partnership for Women & Families – VP
So it is in scope, in other words, for these bullets?

Steve Posnack – ONC – Policy Analyst
I think the answer to your question, the short answer is yes. But it's still a question of what purpose that body would serve, so what would they be governing? And that's really what we're looking for.

Christine Bechtel – National Partnership for Women & Families – VP
Right. I just want to make sure it doesn't get lost.

Steve Posnack – ONC – Policy Analyst
If the workgroup decides that some type of governing body is relevant and specific and succinct and the right thing to do for certain functions' activities, then by all means you guys could talk about the membership and its functions.

Christine Bechtel – National Partnership for Women & Families – VP

So I'll just take that as a yes. I think I'm thinking of it in also different ways, that's certainly a possibility. But if we look at the HIOs and the other entities that are actually doing exchange, should they also meet some requirements around trust and transparency and the structure of their governance.

Steve Posnack – ONC – Policy Analyst
Right, and that would be, I would say, a different governance element that we would consider.

Christine Bechtel – National Partnership for Women & Families – VP
Good. Thank you.

Steve Posnack – ONC – Policy Analyst
That's concrete enough, though.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Other comments or questions?

Michael Matthews – MedVirginia – CEO
I want to call attention to the comments regarding certification and accreditation. Under the general assumptions it says certification or accreditation will be one component of governance and on the following page under compliance and enforcement approaches to consider, so accreditation and certification of intermediaries may be an approach to consider. The whole issue around certification and accreditation I think is very deserving of some in-depth discussion around whether or not those mechanisms fit into overall governance.

Mary Jo, I don't know if you had any comments at this point around your thoughts on whether we take that as a given under the general assumptions, or it's a potential tool of governance under compliance and enforcement. But before we bake that into our overall approach I think it is deserving of some discussion.

Mary Jo Deering – ONC – Senior Policy Advisor
Well, again it is a working assumption by ONC that that will emerge. There has been so much discussion of it in so many areas. The reason that it also shows up on the next page is that in some models of accreditation you actually invest some of the enforcement and accountability in the accreditors themselves and so again there's ways to step through the issue of accountability and enforcement, not taking away the potential need for some higher body. So we're not trying to dictate or propose that we know exactly what that right level of structures and accountability might be and how it might be distributed, but I think you will see, again, getting to the next page, I believe that the word ―distributed" governance, when you talk about governance of governance, that's certainly part of the concept.

Michael Matthews – MedVirginia – CEO
Well again, I'm not opposed to it, but as we move from discussion of it to agreement on accreditation, and it seems like every ... that has certification also has accreditation, we need to just be clear when we're taking out something as a given what it is that we're taking on and what are the implications around taking that on. So when you say that that's a given, I don't know whether you're referring to certification or accreditation or both. That's where, again, I just want to be explicit and clear in our language when we're making these decisions and documenting our recommendations that we all understand what it is that we're achieving consensus on.

Mary Jo Deering – ONC – Senior Policy Advisor
Actually, that bullet may be grammatically incorrect, and I'll look to others to tell me. My understanding is that you certify a product or a thing and that you accredit an organization. Now, I could be wrong. Steve gave me the thumbs up. So again it's not really that we're going to certify .... If you go up to the prior page it was stated more accurately, where we actually said that you know that you might certify the solution or accredit the entities, but yes, again, that is a working assumption. It's up to the workgroup to tell us if or how they see that playing in. But ONC goes in believing that that's probably going to show up.

Michael Matthews – MedVirginia – CEO
Okay. I'm just going to stay on it for one more round. So, if we focus on, under general assumptions, bullet point number three, is the assumption and a given certification and accreditations then, or is it certification or accreditation? If it's certification or accreditation we need to be clear on which one it is, and if it's both let's say ~~and~~" instead of ~~or~~."

Mary Jo Deering – ONC – Senior Policy Advisor
I don't know that ONC at this point – we could say ~~and~~" or ~~or~~," it might be more accurate. What we're trying to signal here is really flexibility. So certainly an ~~and/or~~" might be grammatically better in that third bullet.

Michael Matthews – MedVirginia – CEO
I'm not trying to ... or get into the language around this, but again to be clear, I think we need to hear from ONC take them one at a time. Are you taking it as a given that we're going to have a certification of the solutions? Then are we taking it as a given that there will be accreditation or are we to pick and choose between those two? That's where I'm not sure what your assumptions are.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
I think that ONC has stated their assumptions and we are within our right as a committee to say we agree or disagree with those, and make a recommendation either way. We can make a recommendation that the field and certification or accreditation process is nowhere near mature enough and that we don't believe there ought to be any rule on that. We can say that what we recommend is certification of technical solutions, but we don't recommend accreditation of the entities such as the exchanges. Or we can say that we don't think that certification of technical solutions is right right now because things haven't evolved, and we're going to talk about some verification of the entities that facilitate exchange. I think that's all within our purview. I think ONC is hinting that they believe that certification or accreditation is appropriate. I think it's our job to either verify that or make another recommendation.

Jodi Daniel – ONC – Director Office of Policy & Research
I'll be on and off during the course of the day, but I think that John said that perfectly.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Any other questions or comments? Okay, so that's the scope document. We need to remember that. What I'd like to do is go to the next set of discussions which is to talk about a set of principles for governance. You have in front of you a four page document and I'm going to call your attention to the third page, second point, which is the governance of operational Nationwide Health Information Network submitted to ONC for health information technology by the National eHealth Collaborative health information governance framework. I'm raising that because that document, I would like to suggest, is going to be our supporting document. In other words, we're going to pay attention to everything up until two, but remember that two is there in case there are items in two that we want to promote into one.

So we're going to start off with the top of page one. I want to give special thanks to Carol, who provided this initial draft, and we'd like to walk through it. I'm not going to read every word there, but starting off with—

M
....

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Yes? Oh, that was myself. Sorry about that. First, what is the National Health Information Network and what is its purpose? I think this is a definition that has been used a fair bit of times, including with our original charge to the committee. So are there any questions about the definition? Good.

The second big heading is what is the Nationwide Health Information Network* or its new name, and it talks about the mechanism that ensures the policy standards and services that enable the use of the Internet for secure and meaningful exchange. And it talks about the fact that there are patchworks that

these elements exist and only with a sound governance framework in place can the NHIN serve its intended purpose and deliver sustainable solutions. Any comments on that section? Okay.

The next one is what are the governance principles? Transparency, inclusive participation and adequate representation, effectiveness and efficiency, accountability, distributed governance and devolution—I'd look that up just to double check that that means moving from national to local—clarity of mission and consistency of actions, fairness and due process, these are the list of governance principles. We have a couple of others after that which are principles to consider and with a broader definition of each one of these documents and I think a couple of other add-ons. So why don't we walk through this list to see if we believe that the list of seven is adequate or we want to promote others from the subsequent list in there.

The first one is transparency and openness, and there's a description of that. Are we comfortable with that as being one of our principles? Okay, I hear some rustling. Is that getting ready to talk or just preparing to turn the page?

The second principle is form—I'm going to go down our list before we get to the second page. The second principle is inclusive participation and adequate representation. Are we comfortable with that being on the list? Okay.

Effectiveness and efficiency?

M
John, we'd have to pretty much give up on motherhood and other virtues to not accept these, right?

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Okay. So are there any disagreements with the list of seven, instead of me walking through each one of them?

W
....

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Devolution means essentially moving out to the level of function, so rather than keeping everything centralized. Is that correct?

M
....

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Okay. So now we're going to go to the list of potential candidates, if there are other principles that we would want to include in our set.

Mary Jo Deering – ONC – Senior Policy Advisor
Just as an explanation, the first of these was actually provided to the small group and that's why I think you'll see almost verbatim some of the titles in Carol's list and you'll just have extra test. But then there were also much longer lists to choose from.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
The first one that's on the list that's not on the seven is form should follow function. That's a good point, but do we want to promote that to our list of principles? I'm going to need someone to speak up for it, or we're not going to. Okay, Leslie first.

Leslie Harris – Center for Democracy & Technology – President & CEO
I'm trying to figure out, looking at the seven, and I haven't started this exercise yet, whether some of these are sub-categories under the seven or really new ideas. So I haven't started to do that yet. But I

do have a sense that some of these are deeper statements of the original or clarifications. So I would just ask for that exercise as we go through it.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
So you have three options with each item we're going through. If no one speaks, they just are left off the list. The alternative is to promote it as a separate principle, or the third option would be is to make it as a sub-principle or an explanatory to one of the seven.

Christine Bechtel – National Partnership for Women & Families – VP
It's Christine.

Elliott Maxwell
This is Elliott Maxwell. The longer list was in some internal work for ONC.

W
It was given to them?

Elliott Maxwell
Right. Then the first set of seven principles was then abstracted out when Carol was doing, I think it was Carol, was doing a contribution to say how would we frame the governance issues. So the longer list was developed earlier and was trying to cover and be more self-explanatory for a list of principles that would function for governance.

Christine Bechtel – National Partnership for Women & Families – VP
I want to ask a question about how we think the principles, either the one through seven or the bullets, are going to be used. Because I think the one through seven, you absolutely can't argue with. But on the other hand it's not entirely clear what we mean and how we might use them, but it gets more clear in the sub-bulleted list. By the way, I think this document is incredibly helpful so I appreciate it.

W
I agree.

John Mattison – Kaiser Permanente – Chief Medical Information Officer
I'd like to make a suggestion, to follow John's options, option number three would be to place ―form should follow function" as a sub-category of principles number two and number three.

Christine Bechtel – National Partnership for Women & Families – VP
I think that's actually an interesting approach is to begin to merge these. So on transparency and openness you have the bullet on what we mean and it should be sub under that and it becomes integrated in a little more detail.

Mary Jo Deering – ONC – Senior Policy Advisor
My assumption, and this is certainly up to the workgroup, is that ultimately you would, and maybe we should let Carol speak for herself, but I guess my assumption was that you might have wanted to add the additional text, which explains what the title is anyway and you don't need to wordsmith it right now, but that you would want to blow it out a little bit. Carol, again, I don't want to put words in your mouth.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
I would just say that I think we had always envisioned defining the seven in the way that the others are explained. I think maybe the first exercise is to just see substantively if we think any of these are missing or if they're subsumed in the big seven categories.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Okay, so we've got a suggestion that form follow function be an enhancement of principle two and principle three.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
I don't quite understand it under two, I get it under three.

John Mattison – Kaiser Permanente – Chief Medical Information Officer
The form of the governance to follow the function would help define the representation. So who sits on the governance would reflect their functions in the HIE world.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Any other comments on form and function? Accountability we already have there. Minimization, anyone want to promote or subjugate that?

W
... three.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Number three, yes. Okay, good. Any objections to that? Distributed governance and devolution, we already have.

W
... description.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
That would be a description. Representative governance is number two.

W
I'd actually like to specifically call out consumers in that I don't want to be a one trick pony all the time in this workgroup, but for this purpose I'm going to be. The reason I'd like to do that is because I think this is an area where we hear all the time, oh, this is too technical, it's too hard. We can't find consumers and so therefore we're just going to go with the majority of people who have business interests in the exchange. So I'd love it if we could agree to actually calling out consumers specifically, as Mariann I think has.

John Mattison – Kaiser Permanente – Chief Medical Information Officer
Along the same lines, my comment 15 minutes ago in answer to Wes' question about what does success look like, and my response being representative participants, I would strongly agree that both consumers and ONC and participants throughout the value chain at HIE all have a function to serve and therefore a representative role in form.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Clarity and consistency we have. The next one is prescriptive rules.

Leslie Harris – Center for Democracy & Technology – President & CEO
I'm really wondering when I look at this whether this is a principle of support for innovation, whether a statement here about limiting prescriptive rules to situations where they're critical to do so is really, if you flip it around, a statement that one role of governance is to encourage innovation. I hate to see that innovation point a sub-point because I don't want to speak for you, Carol, but I think we both share a concern that heavyweight governance can crush innovation and that we're very early in the process here. So I'm really wondering whether a role of governance, that in some ways ... frame everything else you do is to look through is this an approach that's going to crush innovation or is this an approach that's going to support innovation.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Carol?

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

Yes, I was going to say I completely agree with that. I think it's an objective of governance. In fact, I think I wrote it into one of the high level objectives for NHIN governance. I would love to see it added in some way— I didn't think the title prescriptive rules really spoke to it well, but I think the concept is very important. In some ways you can get to it, and I think this is going to be true for a lot of these, you can get to a lot of these in the way we define and explain these principles further. In other words, one of the good things of having a couple of sentences describing them is you get to say what you mean. I could see it being a part of effectiveness and efficiency, but I'd be very happy to have it be its own—

Laura Adams – Rhode Island Quality Institute – President & CEO
I think that if we could make it its own that would go a long way toward the participation that we're seeking. It feels to me like there's a significant concern out there that this is going to come out too heavy handed and won't be able to accommodate the innovation that people find so important, and me included. So I do think that there's some reason to consider it on its own.

W
We probably should add both the prescriptive rules and the standardization bullet below it, I think.

Leslie Harris – Center for Democracy & Technology – President & CEO
... minimization, I think all of those go under different but I think they also go under this notion of innovation.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
So we have number eight, which is promote innovation. Promote, foster, facilitate, something like that.

John Mattison – Kaiser Permanente – Chief Medical Information Officer
I think the verb in front of innovation is very important and so others may disagree, but I would say promote and manage innovation. The reason I say that is related to our hearings and the testimony from Mark McCarthy, where he really clarified a lot of things about when it is appropriate and necessary to have a centralized framework for innovation and when it is preferable and more prolific to have a more distributed form of innovation. So I don't want to try and wordsmith that today, but I think to foster and/or promote and manage helps distinguish between a very key principle that came out of his testimony about when and where it's appropriate to centralize versus distribute innovation as a way to promote sustainable and diffusable innovation.

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security
But is that the role of governance? I think my opinion would be that you don't want to retard innovation, but I think that from a governance perspective and specifically regarding privacy and security you also don't want to make the rules so unclear such that there are abuses that end up undermining trust.

Laura Adams – Rhode Island Quality Institute – President & CEO
I would rather that we discuss the concepts of management without including that in the line, in that I think that would be maybe construed as again undue control over that. I think we are talking about the ability to have some control over the innovation, or at least guide the innovation in a certain way, in a way that you just described that we extracted from the testimony. But I would be a little worried about the term ―manage innovation" conveying maybe more than we expect to convey.

John Mattison – Kaiser Permanente – Chief Medical Information Officer
I accept that. I think as long as there's some reference to it in the dialogue below the headlines, that would be preferable, I agree.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
So if we can add a sub-bullet of manage innovation. Okay. We're going to add in standardization under promote and support/foster innovation. Hopefully in the final one we'll find the right word. Any other comments on standardization?

Retention or delegation of authority, does anybody want to move that anywhere or let it fade away? Mary Jo?

Mary Jo Deering – ONC – Senior Policy Advisor
I would just make the observation that it is related to, and if necessary could go under item number five. But it is distinct, and it has to do with a legal principle, as I understand it, which is the authority was given to ONC and there are legal issues related to what you can actually give away outright, what you can allow others to do but say I retain the right at some point in the future to, in the public interest, to fulfill my obligations. So that's why ONC felt it was important to call it, because it's different from distributed and devolution but related to it.

Christine Bechtel – National Partnership for Women & Families – VP
I agree with keeping this ..., because I think there are some areas where federal oversight is necessary, particularly in this environment where we have an enormous amount of taxpayer dollars being made here. So I think it's probably good to have both the existing language around principle five, which is above in the bulleted list as well as something that alludes to the important role that the federal government does have to play. I think we heard a lot that we don't want to be too heavy-handed, there's a minimal role, but there is a role. I think that's important to signal.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
So if we use something like these words under number five, would that work for you?

W
....

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Under principle number five, distributed governance and devolution—

Christine Bechtel – National Partnership for Women & Families – VP
Yes.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
... that there be a discussion of retention or delegation of authority.

Christine Bechtel – National Partnership for Women & Families – VP
Right. So that's what's here, right, in this bullet?

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Yes.

Christine Bechtel – National Partnership for Women & Families – VP
Yes.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Is there anything that we forgot or didn't include in our now list of eight?

Mary Jo Deering – ONC – Senior Policy Advisor
...one item in number two that doesn't show up.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Which item is it?

Mary Jo Deering – ONC – Senior Policy Advisor
If I read correctly, now we're looking at sub-group number two, which came from a white paper done a year ago by a public-private working group, I believe it's the responser bullet that would be on the bottom of the third page. It is certainly similar to inclusion, participation, and representation. It could be

effectiveness and efficiency. It could go a lot of places. I'm not necessarily saying that it's urgent to keep it there, but I did want to point out that it's not really articulated anywhere else. I think the others are obviously included already.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
I think that that would be an enhancement of inclusive participation and adequate representation, so when we explain that, we can pull some of that language. Any other items? We now have a rough draft, where we're not going to try to wordsmith that today, of a set of principles. Is everybody comfortable with where we're at?

Let's see we started at 9:00, it's 10:20. Do we want to take a break or do we want to push forward? Does anybody want to take a break now or should we go into outlining the initial recommendations?

M
Great.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Okay, let's push forward, because I wouldn't know if any of you took a break anyway. Okay, we've got in front of us the documents, for those of you who can see on your computer screen, governance functions gaps and needs assessment. This has been the work of the sub-group. Over the last three or four weeks they have been having a meeting every Friday. I would like to again thank them for their efforts. So they recommended five categories of work, but the first area is would anybody in the workgroup like to make any introductory comments before we start walking through this?

So we've got five categories, which we're going to go through. Those five categories are: ensure privacy and policies for privacy and security; establish other policies, practices for expectations; establish technical requirements; compliance accountability; and enforcement and oversight of the governance mechanisms. For each of these we're going to determine whether the NHIN governance should address the identified gaps, discuss the issues and considerations, and provide preliminary recommendations on whether formal governance or coordination is needed. That's going to take us up to our preliminary recommendation.

After the policy committee meeting then we will subsequently say if we determine that there should be governance there, and we will make recommendations on what that governance should be, by whom, and what. So there are overarching questions. Should there be governance functions for the Nationwide Health Information Network that defines policies and practices for trust and interoperability, defines technical requirements, addresses conformance with the requirements and policies for trust and interoperability, and defines how organizations should be accountable for compliance and accountability and defines how enforcement should be addressed. So, I was just wondering why those five questions didn't correlate with the five categories.

Mary Jo Deering – ONC – Senior Policy Advisor
I think they were supposed to, sort of. Mariann?

Mariann Yeager – NHIN – Policy and Governance Lead
I think that when you get into the substantive functions themselves some of those concepts crossed multiple categories, so it was important to call out the overarching questions that actually may be applied in the five categories for the functions, if that makes sense.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
It works for me.

Mariann Yeager – NHIN – Policy and Governance Lead
Okay, good.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director

Any questions, comments about the overarching questions before we jump into the meat of these? Okay. First category: ensure privacy and policies for privacy and security. The governance objective is to assure that sufficient privacy protections and safeguards are in place to ensure trust in a Nationwide Health Information Network. The proposed function of the governance is that there would be authoritative governance and/or coordination mechanisms to define privacy and security policies and practices for the nationwide HIN that at a minimum are based upon HHS privacy and security framework and reflected in technical design. The rationale for that is that variance in state laws and insufficient level of specificity in national privacy and security laws creates a burden and potentially impedes exchange of health information on a nationwide basis. So I'm going to ask us to focus in on that section first before we go down into the key issues. Any comments on that section?

Elliott Maxwell
Just one in terms of clarity, in the key issues and the considerations, coordination is a form of governance as opposed to being a separate category. I think the point that was being made was is this going to be a coordination function or some other form of governance as opposed to one or the other, just for clarity sake.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
I had actually the same question. I was wondering why this was a versus. Also it seems to me that policy making somehow should come before the issue of coordination or policy setting. I don't know, this has morphed quite a bit so I may be missing something.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Mariann suggested that maybe the wording is coordination versus other. Let's spend a little bit of time, because this is a theme that runs really throughout the document, is the issue of what do we mean by coordination, what do we mean by something that may be more prescriptive or perhaps centralized.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
I would say I don't know that it's prescriptive or centralized. I think it's really a question for a lot of these areas that policy making is happening in more than one place, even at the federal level. More important, it's happening, or potentially happening at more than one place. That requires a level of coordinated action in order to be useful to participants and I think some of this, and it's kind of a chicken and egg thing, I think some of this becomes clearer when you start to really think about a walk through a complete example of where's policy making, for instance, today taking place on privacy and security and you start to see that there's not a place and that there's both a level of accountability for it and need for it to be clearly specified and defined and also a level of coordination that's necessary so that people have clear guidance.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Let's see if I can frame what I think I'm hearing. We may be setting a false dichotomy between coordination and other governance that where there are established mechanisms and gaps, so gaps and established mechanisms, that we need to coordinate between those established mechanisms and in an additional different kind of governance process fill the gaps. Is that a fair statement? So maybe we need to say that, we don't have to do that today, but we maybe ought to say that somewhere in an introductory paragraph. Elliott?

Elliott Maxwell
There's another subsidiary question to that in thinking this through. One is, from the standpoint of the working group what should ONC be doing and were there other mechanisms. This has largely been focused, and rightly so, on ONC's role, but there may be recommendations that the working group makes that go beyond ONC's role and points to other things, as the Tiger team, for instance, might do. So the subsidiary question is who in the federal government might play that role beyond ONC if there are gaps.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Right, although we're not going to get to—

Elliott Maxwell
Not ....

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Not in this session. So let's go back to one. I'm looking at one, I think one is an important point but I don't think that the key issue is stated correctly.

Mary Jo Deering – ONC – Senior Policy Advisor
It almost seems like that could be elevated, as you said, to part of the preamble, the introduction. It is still cross-cutting and that it is perhaps not a specific recommendation under this sub-section but that line, 1.1, becomes extracted and added somewhere up front, I heard you say.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
But we do need two kinds of recommendations: who coordinates and who fills the gap and how. So that really sets up the key issues for which we need to then have a recommendation. So is everybody with me on that one?

Mariann Yeager – NHIN – Policy and Governance Lead
Just to clarify: We could have a placeholder here to at least highlight an issue that would be discussed further in the next phase of the group's work that would get to the how and who, is that what you're suggesting?

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Yes, that we would have a placeholder that really—it's not versus; it's coordination and gap filling, is the key issue. I don't think it's governance gaps. I think it's gaps in policies and procedures.

Mariann Yeager – NHIN – Policy and Governance Lead
It could be a gap in any one of the functions of governance.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Right. Okay. Any other comments on number one, 1.1? I feel like I'm writing rules when I say 1.1. I think the considerations would have to be modified to reflect that and enhanced about identifying gaps in functions. Can we move on to 1.2? Different approaches for privacy and security, should there be different types of mechanisms for privacy and security? I think there should be different approaches for privacy versus security. Does anybody want to talk about this one?

Mary Jo Deering – ONC – Senior Policy Advisor
I will just point out that in the testimony one or more of the—I may be attributing it wrong, but anyway, one of the speakers as noted there, actually I think it was Jim Golden of Minnesota, said very explicitly the government should establish nationwide security requirements as part of governance rules. However, the variability and the key role of states and privacy issues, you need to approach that differently.

Mariann Yeager – NHIN – Policy and Governance Lead
It was the perspective that was brought forward in the testimony from several states that they made the distinction from their perspective and we weren't clear whether or not the workgroup wanted to carry that forward and look at privacy and security differently, separately or not.

Mary Jo Deering – ONC – Senior Policy Advisor
So this may be the question I was asking prematurely earlier today, states do have very different privacy laws and the HIE ... up, most have made some fairly serious decisions around privacy. So I'm assuming that we might approach privacy differently and that some of the current thinking of the Tiger team, for example, would be best practices or higher level certifications, but they would not be rules. If that's what we're thinking about then I'd probably agree with that.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
And just to clarify, higher level certification for privacy or for security?

Mary Jo Deering – ONC – Senior Policy Advisor
Privacy. What I'm saying is if states have rules and the decision of the Tiger team is exchange at a minimum ought to have the following, it's possible to set a floor for privacy beyond HIPAA, but I think it would be really difficult.

John Mattison – Kaiser Permanente – Chief Medical Information Officer
Somebody please correct me if this distinction is a false one, but it seems to me we're mixing two issues. One is the relationship of privacy to security, and the other is the challenge of having variability state to state. So if I can propose that if we split that into two separate issues and there be a minimal floor of privacy set at the federal level, which states can and do exceed in their statutes, and that security is in fact responsive to the privacy requirements. So the floor for national security would support the floor for national privacy, and any additional state amendments, enhancements, additions to that floor would be the obligation of the state to manage both the privacy requirements and the security solutions for those enhanced requirements.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
... I think that we are talking about interoperability across states and between the federal government and states. It's not particularly conducive to say that we're setting a floor and the 51 entities here, not counting territories, have to work out bilaterally how to implement the minimums across their state. I think the hand we are dealt is that states set individual levels for policies and all we can do is to urge ONC to continue what it's been doing and try to find levers for making those more uniform, but it would be foolish to believe they will become uniform.

Security, however, falls into two categories. There's a broad, the federal minimum, as John describes it, covers a whole lot, but to the extent that we are looking for security software to implement policy, we have to describe a mechanism for doing that across states. As some of the people who are on other committees with me know, this is an area I'm very concerned about because it's one of those things that's much more easy to do technically than it is pragmatically. But in setting the charter for governance I think we have to set the charter as abetting or aiding interoperability across states.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Mary Jo?

Mary Jo Deering – ONC – Senior Policy Advisor
I only wanted to make one additional observation, that in many people's conversations it's not only the security hardware to implement the policies, but it's the practices down even inside, however far those might get, at some other point in time I think you'll come up to a question which says how far inside a node should governance reach. Again, I'm only putting on the table what has been raised in various settings, and I believe it was actually brought up in a hearing as well, that it's security practices as well as the hardware.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
I'm actually struggling with another piece of this, which is that we are, I think, in the way that we framed this we've minimalized security by defining it as security necessary for privacy. But there's also security that's necessary for data integrity and other functions of the system. So, I think differentiating, splitting out privacy and security may be the only way to really address both appropriately.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Wes agrees.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
I think we've answered—

W

I think Wes makes a very, very critical point and it's a point I've tried to make a couple of times too, which is that our objective should be interoperability, both when speaking of policy and when speaking of technical aspects, whether it's standards or security requirements. In some ways back to the minimization principle which is, and I think I mentioned this on Friday, if it's not required for interoperability then it doesn't need to be ....

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Right, but you'd like to know that what I put in the record for my patient in Paducah is actually what's transmitted to Eureka.

W
Right. I'm not speaking about the ... data integrity. I'm going back to Wes' point, which was that interoperability is a really important paradigm for us and we tend to only think about it at a technical level. But there's a level of policy interoperability that I think Wes is heading to when he talks about our objectives and the scope of this work that I think is critical to be mindful of.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
So I'm suggesting that we have already got an answer to the question that we have in 1.2, which is I think that we believe that there should be different approaches for privacy and security. Then with the same principle but different approaches, which is that of the objectives should be interoperability of policies and practices for privacy and security between states. I'm just wondering a little bit about the construct of considerations and objects. Since we're making a report to the policy committee I'm wondering if the question should be, do they agree with the fact that there should be separate approaches? That's less agnostic than it sounds like we are as a committee.

W
Are we saying they're really separate or are we saying the scope is the same for both, which is interoperability?

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Others can speak to that, but to my mind I never want to miss an opportunity to emphasize that they are different animals, and while they're linked they need to be looked at separately. It sounds like we're conflating the two.

Leslie Harris – Center for Democracy & Technology – President & CEO
I'm a little worried we're conflating the two because—

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
For us simple people, what's conflating mean, without having to look it up?

Leslie Harris – Center for Democracy & Technology – President & CEO
It means we're thinking about security just as an enabler of privacy and not of the security of these systems and the data integrity and all the cyber security questions that are in privacy questions.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
I think that we should follow Carol's advice here. I think I'm going to follow it and get back to where we are, but it's worth the trip. As a predominating principle for the agenda of items covered by a governance body, I would say that if it doesn't support, enhance, or further the cause of interoperability across state boundaries and the other boundary you mentioned, it's probably not appropriate for the agenda.

Now the question is does the security, other than that necessary to maintain privacy, enhance that interoperability. Clearly most kinds of security, perimeter, having locks on the doors and getting rid of the passwords of discharged employees and so forth does enhance privacy. There are a few items that could arguably be said only enhance continuity of operations or integrity of the data. I would argue probably that they go to the trust that's necessary to be interoperable. So that I want to trust that if the

patient thinks there is data somewhere that I should be able to interoperate with that it won't be gone down the drain somehow.

But that's a discussion that could be had. I still, for the reasons that John outlined, I still think that privacy and security should be identified as separate items, both should be treated with the point of view that our interests, the interest in governance of them is constrained by those issues that enhance interoperability.

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security
When you say ̶constrained by interoperability" back to your earlier points about availability and integrity do you lump those two as being interoperability as well?

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
I was arguing that they could be under trust. Interoperability depends on trust and trust depends on— We know that physicians, for example, the probability that they'll attempt to retrieve records is in inverse proportion to the time it takes and the likelihood they'll get anything.

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security
So it's provider trust rather than patient trust?

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Oh yes, provider trust is definitely part of the equation, you're right.

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security
....

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
I'm not going to release data that's going to go to my competitor unless I have reason to trust that it's not all being released, that it's specific to a case, and I'm not going to use a source that I consider flaky and so forth. But you're right, we normally think of trust in terms of patient trust and this is another dimension of trust.

John Mattison – Kaiser Permanente – Chief Medical Information Officer
I like the way you framed it, Wes. Can I call something out and ask a question? The accountability for integrity has been a subset of trust under Carol's rubric of it must support interoperability and trust in order for it to be on our agenda. Do we need to call out specifically preservation of data integrity under the rubric of trust in the documents?

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
To the extent we have for examples, I would say so. I think we're getting closer to defining what the committee would define for itself at that point though.

W
Yes, and I just want to point out that we should not redefine the ONC privacy and security framework principles which I think include accuracy and data integrity in some form or another.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
So in developing that text we can pull from the framework. The issue I think before us is that we will suggest that from a governance perspective that we will separate privacy and security. Is there agreement on that? Okay, I think we can move to 1.3, the role of the states recognizing levels of governance fitting within a national framework, and the options are defer to state authorities or federal level coordination across states to facilitate a common set of privacy and security policies. Those two are not—

W
... different types of options were discussed during the testimony in the hearings so they're not put forward as recommendations—

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Right. I'm just trying to think whether or not they're mutually exclusive.

W
They may not be.

M
They're definitely interdependent.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Interdependent, yes.

Leslie Harris – Center for Democracy & Technology – President & CEO
They're interdependent. It feels like there's deferring to the states, there's coordinating, getting a common set of principles, and there's deferring to the states to the extent that they meet some kind of minimally necessary .... So I feel like we're missing something here. I can imagine that this body says security has to accomplish the following, and then states are accomplishing it differently and there has to be somebody who's saying— I'm trying to put this in the framework, not that I particularly like it, but European data exchange framework, since I come to this from a different place, where there's an adequacy of different countries as to whether or not the EU will exchange data.

So it's not a total deferral, nor is it a common set of policies. I think it's that you're defining these things in terms of security has to accomplish the following things and then it's whether or not—each state could be doing this differently possibly. These are not technical standards, they are performance standards—I think now I'm putting on my cyber security hat – so they're performance standards. Those performance standards may well be different in different states, but this gets back to whether we're certifying and all those questions, but these two bullets don't quite, unless it's a common set of—it may be the second one insofar as it's a common set of performance standards— ... policies, we're going to make sure that everybody is installing the same software, and I don't think that's what we want to get to.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
I was just going to say I don't understand the text in this box either at all, but I think here, again, and I agree with you, Leslie, wholeheartedly, our ... will be the role of the states thinking about that in the context of what's necessary for trust across the networks, for interoperability of trust, if you will. So while ... the issue of let's say data integrity several times, it's not that there's a specific policy or practice that's going to be issued for what data integrity needs to entail, but there may be a performance standard that says you can achieve this level of performance in order to be trusted across the network. Again, doing it in a way that is interoperability focused really becomes the ... for looking at a lot of these issues.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
So in looking at it from the state level I think one of the realities is that, has it been ten years since we've done the privacy rules, pretty close to that, and every state law in privacy that has been issued, there is, I'm guessing, based upon my experience at the state level, there is a knowledge that goes into those negotiation sessions on those privacy laws that there's a federal floor, and that going into those laws legislators are willing to give up items based upon the fact that they know that the federal law will cover. So they compromise and add in other provisions. We have to think about this whole network of privacy as being basically a state-federal system. So the dichotomy that's there, which I think we're all trying to struggle with, of defer to the states might better be, as I think Leslie and a few others have talked about, framed as coordinating between the state and the federal authorities.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Maybe one way of addressing this is to take it based on the question you raised at the hearing, which is what are the obstacles. So to the extent that the obstacle in privacy is a set of variances between state rules on consent and other things, what would the working group recommend to address that obstacle, that drives the recommendation, as opposed to the theory about it, because the goal is to promote

exchange. What's in the way in this area as an obstacle to exchange, and therefore what you need to do and there may be lots of mechanisms. But that's the framing of the question, how do you get to a position where you address that obstacle?

I'm sitting here doing what ... had to do, which is thinking of worst case scenarios like suppose some state says that any provider who ever provides data electronically must be able directly to give the patient a list of everybody who looked at that data once it went out into the network. What I realized is that we already, we have this group of vendors who regularly cross state boundaries, and they deal with the variability in states' requirements in several ways. One, they design software that's adjustable. Two, they work with their clients to find interpretations of the state policies that are implementable, such as, for example, agreeing that prohibitions on information about AIDS extends to filtering data by codes but not to interpreting the text and data the way a person might interpret it to infer that a patient has AIDS.

And that what they are doing is a process that this governance body is going to have to take on in a more formal basis, in the sense that it is in fact coordinating the federal and state requirements by which it means establishing a set of standards and procedures that provide the necessary capability to adapt to state requirements, or, simply declaring that the state of Jefferson in southern Oregon, we can't work with them. But fundamentally there's a pragmatic nature to this that the governance committee has to take on, and going back to the principles, the goal is to enhance interoperability, it is to create a uniform approach that can be used in various states to meet the state requirements. I can always tell I'm rambling, or else the phone line died.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
No, actually you've provoked thought, at least in me, of how do we express what you just said.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Yes.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
I'm going to suggest that I think we have the essence of what we want to say in this, so we need to try to put some words there.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Good chairman technique.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
So can we move to 1.4?

Mary Jo Deering – ONC – Senior Policy Advisor
What I was going to say is also that remembering that you're going to talk to the privacy and security Tiger team which is looking at this, and while they're not explicitly addressing the federal-state aspect, they're looking at the problem itself and they're still working through this, so again it may be that there's additional clarification or specific recommendations that come out of that that might tilt us one way or the other.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
I hope so.

Michael Matthews – MedVirginia – CEO
I'd like to call attention to the use of the term floor" in our public presentation of our work. I think it has a negative connotation, that well, it's merely acceptable but hopefully ... will do better. I think if we can substitute something like required elements, something like that rather than floor, I think will go a long way towards promoting trust.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
I think that term or phrase could get under ... easily.

Laura Adams – Rhode Island Quality Institute – President & CEO
I very much agree with that idea. I think what we're talking about, rather than a floor is that idea of that imputable core at the center, so it's more along those lines than it is the notion of barely getting by.

M
Core or uniform.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
So we will change that line of our—

M
I wouldn't say uniform. That implies not just ....

M
Okay, so core.

Michael Matthews – MedVirginia – CEO
Just so I'm clear and not off base, the federal ... what we're talking about is the state's participation in the Nationwide Health Information Network, correct? It is possible, I believe, unless Mary Jo's requiring it in her awards to the state, that a state in fact could operate in HIE that does not qualify for participation in the National Health Information Network. So I'm looking at this all in the context of what does it take for the state to be in HIE and then what would be their set of requirements and performance expectations and so forth outside of that subject to wherever we end up on the accreditation and certification issue, I believe then that that's where we have the appropriate deference to the state and whatever they'd like to do at that level.

Mary Jo Deering – ONC – Senior Policy Advisor
I have to make two clarifications. The first is I don't make awards to the states, thank you. I wish I had that authority. Maybe you did say ONC and I heard you say Mary Jo. Michael, I think that the thrust here is actually not as you've described it, that this is purely about how a state entity, how we might relate to an existing or proposed state entity. Because remember what we're trying to really do is encourage interoperability across all boundaries and jurisdictions. So it's not the state solely as having a ... because in the future there may be many states that don't have state HIEs and still need to ensure interoperability across those states. So I think that ultimately the impact of whatever we do here will also fall on this use case that you described, or the scenario that you described, but that certainly wasn't the total universe I think in which this was addressed.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Other questions on the role of states? Can we move to 1.4? Defining the depth of policy compliance, are there policies that should apply through the chain of trust between and within the nodes? Is there any other answer but yes?

Mariann Yeager – NHIN – Policy and Governance Lead
I think one of the questions that came up in the hearing was how far down the expectations for trust would flow and to what extent there would be some accountability measures or governance that applies, all the way down to the point that a provider submits information or is it just the entity facilitating the exchange? I think that has been a question that I know has come up internally but falls in the hearing.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Is that a general question that should go under the accountability and enforcement rather than under the privacy and security?

Mariann Yeager – NHIN – Policy and Governance Lead
It could. It could be. I think it's one of those scope questions about the extent to which policies will be defined and where would the requirements apply.

Mary Jo Deering – ONC – Senior Policy Advisor

... showed up here first is that— I'm going to try and channel several people or several entities or several perspectives. On one hand there was testimony and there certainly has been expressed in other venues a very strong feeling that any governance that is created through rule making should only be between the nodes. That's something that some people have stated pretty clearly in various settings. Others do feel that there are certain things that do need to ... and it usually happens to be in the areas of privacy and security that that's felt more obviously. That's not to say that the question does in fact address issues of interoperability and things that are not purely related to privacy and security. But it's more obvious in these areas that you might need to consider what actually happens down at a lower level.

Mariann Yeager – NHIN – Policy and Governance Lead

Then that affects are you looking at some assurances that there are certain types of privacy and security practices in place within that entity and how far do you even go in validating that those elements are in place.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director

I'm trying to think ahead. So what would be the answer, what would be the recommendation that we would make if the answer is yes?

Mariann Yeager – NHIN – Policy and Governance Lead

One option would be to say that the policies established for the nationwide health and information network should only apply to the nodes and those entities facilitating the exchange of health information and other recommendations could be that their policies that not only apply to the nodes, that there may need to be assurances that there are in fact practices in place within that entity and that they carry down those policies in all their subsequent relationships and points of connectivity all the way down to the provider submitting information.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director

So thinking about making governance recommendations, the issue is should we recommend as a committee that governance should have authority of over not only those things that happen between the nodes, but where they are critical to build trust, that they would also influence what happens within the node.

Steve Posnack – ONC – Policy Analyst

I think we may need some additional clarity around what we are talking about when we talk about a node. I think there are various views of what nodes can be. If you take the shiny example, shiny could be the node. Whereas, the RHIOs that make up shiny could also be nodes, because they're representative of a number of entities within those little RHIOs, I guess, for lack of a better word, and I don't know, at least from my personal perspective, that we are presuming right now what a node looks like.

John Mattison – Kaiser Permanente – Chief Medical Information Officer

What I'd like to amplify on my last point is that we need to ... the task of defining how a delegation evolves from national HIN to an HIO and to a .... I think that's a very ....

Laura Adams – Rhode Island Quality Institute – President & CEO

I couldn't actually hear anything that John just said.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director

Good, because I thought it was me. John, could you try again? There was a lot of disturbance on your line.

John Mattison – Kaiser Permanente – Chief Medical Information Officer

Sorry, I'm going through security at the airport. What I was saying is that how we ... from the national governance process to mega nodes and sub nodes and sub sub nodes I think is a rich area that probably requires some off line work to really get to a meaningful answer.

Steve Posnack – ONC – Policy Analyst

.. maybe one illustrative point which folks may disagree, this is Steve Posnack again, it may not be an illustrative point at all. I'm channeling Christine here, which is a dangerous thing. The point that she raised earlier, her point about consumers being part of I would call some type of nodes governance structure, she was bringing up that point that we would potentially make a recommendation that that would be a prerequisite requirement that this entity includes consumers as part of their function. If the entity isn't that type of entity where consumers could readily participate at Kaiser or some of other type of integrated delivery system, and they're the node, how does that work?

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director

I think I maybe want to take us back to Carol's proviso that—if we could scroll up a little bit, I want to say it the way we have it up here, something about being restricted to what's needed for exchange for interoperability. There's a common objective to promote trust and interoperability so we're only really talking about, the question is if our goal is to promote trust and interoperability in exchange, to what extent does this governance need to address the issue within nodes? Is that the question?

W

... question, correct.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director

Okay, did you catch that?

W

Yes, I will.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director

Then we will make a recommendation about that. Is everyone comfortable with that?

Michael Matthews – MedVirginia – CEO

John, I'm comfortable with it. I think I just want to put an exclamation point though that we do not have governing authority over the states that are in position of those requirements, but only to the extent that they want to be a node in HIE and therefore would have some kind of requirements for that standard set of policies and standards and so forth. The wording doesn't need to be changed from what's been put up there, I don't believe, but I just wanted to make sure that that point is accepted.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director

Let's see if I can rephrase your point, so that the states have one of two possible roles. One is as a generator of rules and laws that govern both exchange and privacy and security, and that we're addressing in 1.3, and then under 1.4 there's a possibility for a state to be a node. In that context we would expect that the state would have to meet the requirements of any other node. Just because they're a state doesn't mean that they would be deemed to meet all those requirements.

Michael Matthews – MedVirginia – CEO

Yes to all of that. In fact unless they want to be a node there's no reason for them to ... other than that's just a gold standard that we're establishing for HIE interoperability.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director

Okay, so we have a footnote now. Anything else on defining depth on policy compliance? Okay, let's move on to— Yes?

John Mattison – Kaiser Permanente – Chief Medical Information Officer

I think in our off line work it would be helpful if we defined what we believe is in our purview as well as what is out of scope in terms of any governance ... nodes outside of the National HIN ....

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director

I think we lost the last part of what you said, versus—

Mary Jo Deering – ONC – Senior Policy Advisor
I missed the first part.

John Mattison – Kaiser Permanente – Chief Medical Information Officer
I'm just suggesting we define what is in scope and out of scope.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Okay, I think we need to remember that when we get back to doing the recommendation under this section. Anything else under 1.4? Okay, liability. Should the issue of liability be further studied to assess the ... relevance for governance mechanisms?

M
Whose liability ...?

Mary Jo Deering – ONC – Senior Policy Advisor
I'll explain why we even bothered to put that in at all. It was recognizing that in fact it may be that liability is just, well, we know liability is very different in the medical field, should we even make any effort whatsoever to address this? Should we just recommend further study of it because it is so complex and no one really does have a clear feeling of it? So it's there not to suggest that you need to make a very explicit recommendation about liability, other than is it important enough that it's one of those follow up things that you recommend the department take a look at to see if it would be useful. That was our intent in encouraging it here, not to direct you in any direction.

Leslie Harris – Center for Democracy & Technology – President & CEO
You're saying the department look at it outside of this question of governance, or in the context of trying to decide who within this interconnected network is liable for various—because that is an enormous task.

Mary Jo Deering – ONC – Senior Policy Advisor
Specifically relative to governance mechanisms. It's still a huge body of work, or it could be. I don't know, maybe not. But we just want to give you the opportunity if you thought this was something you needed to be looking at or for now we just set it aside.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Let me suggest, if I can, that we would take 1.5 off the table right now, but put a pin into it so that when we do issue the report we'll say, here's an issue that we identified but we felt that it requires further study by the department before the governance implications could be fully understood.

Jodi Daniel – ONC – Director Office of Policy & Research
I apologize, I've been out of the conversation. I'm just jumping back in. So Mary Jo, tell me if I'm talking out of turn here. But the thought that I have with this is it was very intriguing about the discussion about the financial, the credit card industry and how assessing who would be liable when there's a breach or a loss of data or inappropriate charges, how setting the liability risk on an entity that was able to protect against that risk sort of shifted their thinking and their way of securing the data.

So I think there's something interesting here when we're talking about governance as to who's liable if there's a loss of data or shifting away from a patient in some way. Is there something there that might be an area we should explore because it might affect how different solutions are developed or who's being overseen and who can best protect against a risk—

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security
Can I suggest that the other piece of liability is penalties that already exist within HIPAA and the penalties associated with inappropriate disclosure and things of that sort. And I'm wondering whether maybe what we need to do is try to marry the two concepts to make it clear that a bad actor would have liability of some sort potentially under HIPAA or otherwise.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
So not wanting to get down into that issue, because what we're really looking to is the governance implications of that, and the governance implication is who should determine where liability should lie.

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security
We know we have a penalty structure under HIPAA that's going to apply based upon what would potentially be the issues that would arise with respect to governance.

Leslie Harris – Center for Democracy & Technology – President & CEO
I'm a little bit worried about our somehow thinking we're going to take on who should be liable under law. If we're talking about private civil liability, a patient comes forward— I guess I'm having trouble trying to parse out which liability and I've heard Mark's thing about the financial industry for a long time and I'm just worried we've got a tail wagging the dog and we don't know which dog we're talking about here, because it's not the financial industry and it's a very different question. We have law now. We have breach law, HIPAA.

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security
That's to my point, which is why don't we make it clear that there are laws that would typically attach when somebody does something inappropriate. Governance talks about how we try to oversee all of this, but what happens when somebody breaches their obligation, I think that we do have laws that—

Leslie Harris – Center for Democracy & Technology – President & CEO
There are areas the law doesn't necessarily apply to, and then the question is a different question of liability which is, does this body have power to enforce the policies that it has created and if so what is that enforcement mechanism and what are the remedies? I'm assuming what we're not talking about here is who's liable when somebody goes into court and sues you because they lost your data. I just don't think this body has either the expertise and that's going to get developed by all kinds of trial lawyers over the next ten years. So I just see liability as either there's liability under existing law or we have gaps here that have to do with any kind of actual policies that you have to comply with and you fail to comply with them.

Elliott Maxwell
I think that with respect to governance the liability issues are, if there are standards or certification and the like, how is liability determined. So it's not the working group saying you're liable, you're liable, you're liable, it is liability is an issue that the governance mechanisms need to take into account and an earlier discussion was how does that liability be thought about in terms of innovation, in terms of the ability of the parties to make changes and to protect those innocent parties in exchanges. So it's a set of principles and it's a set of instructions to the governing mechanism as opposed to a determination of who's liable.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
I would suggest that that looks like it belongs under 4.10, redress remedies and sanctions, rather than just—

W
... that we want to take it off and that's where we should be taking it off.

W
Right.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Okay, so can we move that under there?

John Mattison – Kaiser Permanente – Chief Medical Information Officer
One other small piece on that is the ... assign any liability when information is transiting the National HIN.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Okay, so you're talking about the traceability of the information when it gets into the HIN, when it's transiting?

John Mattison – Kaiser Permanente – Chief Medical Information Officer
Exactly. I think that the governance mechanism has some oversight role that that traceability is available, ... and accessible.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Okay. That's an enhancement of that piece, but are you comfortable with us moving that to—

John Mattison – Kaiser Permanente – Chief Medical Information Officer
Yes, I do. I just wanted to add that piece, that I agree with moving it.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Okay. I think that takes care of category one. I'm going to try to push forward straight through until noon, when we'll take a break. So shall we push on to category two, establish other policies, practices, or expectations for the national health information network. The governance objective is to assure that any other policies and practices necessary for trust and interoperability beyond privacy and security policies and practices addressed above are defined to enable adoption of the health information network, i.e. liability again, coordinated breach notification, dispute resolution and other obligations.

The proposed governance function is that there should be an authoritative governance and/or coordination mechanisms, and that may be the right way to phrase it, to define other types of policies and practices for NHIN above and beyond privacy and security that are necessary to assure interoperability, trust and to address barriers to adoption of the HIN. The rationale, these issues are largely addressed through contractual arrangements. The diversity, complexity, and sheer number of contracts is the potential barrier to exchange. In addition there may be other issues that are not addressed in contracts that may be necessary to promote use of exchange.

Any comments about that overarching section, those three boxes, actually four with the title?

Mary Jo Deering – ONC – Senior Policy Advisor
I just wanted to add something to the rationale and I'm going to probably sound like I'm channeling Michael Matthews here, which is that certainly this was behind the creation of the DURSA, is that the parties said we cannot do one-off point to point agreements on all this kind of stuff that's really absolutely critical. So we at least are going to agree to come together and do it under one contract. So it's the same kind of logic. Again, I'm not trying to promote DURSA per se, but it was exactly that logic.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
And it seems to me this is a question that I didn't get a chance to ask Michael, which is that to what extent does—what are the limitations in scope for DURSA? So when we say methods other than contracts, perhaps we mean methods other than contracts including DURSA be considered to address the need for these other types of policies, practices or expectations.

Michael Matthews – MedVirginia – CEO
Are you asking for my comment on that?

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Sure.

Michael Matthews – MedVirginia – CEO
I think that would be a good inclusion.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Okay, any other comments on this section?

W
John, can you repeat your modification?

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Should methods other than contracts like DURSA—

W
Isn't DURSA a contract?

M
Yes.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Other than contracts like DURSA. DURSA is a contract, correct?

W
Yes.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
I think maybe not like DURSA.   Including other contracts including DURSA be considered to address the need for these other types of policies, practices, or expectations. So there's—

W
This is the confounding thing that goes on with the DURSA. The DURSA is a contract to enforce certain policies, as all contracts are. It isn't the place where the policies necessarily get made, so I just want to be sure that we put contracts in the realm of an element of enforcement, not as its own thing under governance.

Mary Jo Deering – ONC – Senior Policy Advisor
I want to ask a question of possibly Mariann or Michael, and it's a point of clarification here. It seemed to me that as the parties came together in negotiating the DURSA that they actually felt they were creating policies, not just enforcement mechanisms. Again, I may be wrong but I just wanted to make sure I understood.

Mariann Yeager – NHIN – Policy and Governance Lead
I know Michael Matthews can probably speak more to this, but there was a very delicate balance that the group made in developing the DURSA and trying not to set national policy in the agreement, that they did in fact identify areas where they had to mutually agree to do business a certain way in order to facilitate the exchange of information. So the question is, should there be a governance mechanism that actually defines those policies that are necessary for national health information exchange outside of just privacy and security, because there were other areas where that group did in fact put forward a working arrangement for how they would conduct themselves and there may or may not be another agreement that exists out there.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
What I think I'm hearing is that policy, it's kind of like ... policy is as policy does, that there are issues that we understand need to be defined that will not be defined with the stability of a multi party legal agreement. So in that case the legal agreement describes the obligation to follow the policies that are developed by a mechanism that is external to the agreement itself. There may be a few issues that that general approach of agreeing in writing to follow policies to be determined elsewhere doesn't org, that is, there may need to be things that have to be part of the agreement itself.

I think we have to allow for both cases. We have to allow, and I believe that the majority of the issues that come up under governance will be those that are delegated to the governing body in the legal agreement, maybe all of them. But somehow I suspect that the governance body has a role in making

modifications, at least proposing modifications to a legal agreement as well as in executing its authority under the legal agreements to set policies and standards and protocols and proper forms of addressing and whatever else comes under its purview.

John Mattison – Kaiser Permanente – Chief Medical Information Officer
Wes, you just described how the ... committee manages evolution and adaptation of the DURSA going forward.

Michael Matthews – MedVirginia – CEO
I do have Steve Grabely here with me and I think he can also add some perspective. Steve?

Steve Grabely
Good morning. Wes, to your point, the DURSA says that the parties are governed by applicable law, so to the extent that rule making occurs then automatically those requirements would be translated to the signatories as part of the legal requirement. I think that we've already built in a mechanism to accomplish the point that I think you brought up. I want to reiterate Mariann's point, which is that the DURSA did not attempt to make national policy. There were a number of issues that we framed up for ONC for guidance that we determined to be policy, and in some cases in the absence of any body of work at all the DURSA does contain some specific provisions that the parties needed to go forward. And the two examples that come to mind, one is dispute resolution, where the parties did agree upon a fairly robust dispute resolution process, and to the extent that that becomes a subject of rulemaking it would be preempted, I suppose, by the applicable law provision.

Then the second is this issue of liability. I think I agree with most of the comments about liability being a function of existing law. The DURSA doesn't try to address that. What the DURSA does is try to talk about how the parties intend to allocate liability, which is a fairly common contractual provision. So whatever the liability is under applicable law, the parties, their contract talks about allocation of that liability to the participants in the contract. Again, rule making or legislation could change that, but then it would be incorporated by operation of the applicable law provision in the DURSA. Thank you.

Leslie Harris – Center for Democracy & Technology – President & CEO
I guess I'm having a hard time understanding that. If there's a law and the law holds specific parties liable, which is what we have right now, it's not entirely clear to me how a contract reassigns the liability to other parties. The DURSA existed before we passed the new amendments to HIPAA, before we passed the breach laws, so I'm just having trouble understanding what that means. If what you mean is that we may, at some point, pass law or rules specifically on exchange, then maybe I understand it. The DURSA was written in the absence of any law. We still don't have much law as it applies to this kind of exchange.

Steve Grabely
I'm happy to take this off line with you, if you prefer, but the DURSA was not written in the absence of law, you have HIPAA and you have state law. There was not, and there still is not, you're correct, any definitive federal legislation specific to HIEs. But there certainly is plenty of applicable law in privacy and security.

Leslie Harris – Center for Democracy & Technology – President & CEO
I understand that. I don't understand how by contracts you get to decide who's liable under a federal law for, say, a privacy violation. It seems to me that that's going to be enforced out of the parts of HHS who enforce and they're going to decide – or maybe I'm just misunderstanding.

Steve Grabely
Maybe I'm misspeaking, because I'm not saying what you're hearing. The DURSA does not attempt to, and nor could it, preempt applicable law. In fact, the DURSA specifically relies upon applicable law. There are situations, and again this may be better off line, but given the complexities of data exchange within the exchange context, and it may be contextual specific, but as a DURSA workgroup half of which were very knowledgeable attorneys, as they sat around and talked about the possible scenarios that could arise within the exchange context, it was clear that applicable law doesn't address each and every

one of those to their satisfaction. So taking applicable law as the starting point, there were some instances where the parties wanted contractual language that clarified how existing liability, which is a function of law, might be allocated among the parties. And again, the parties can do that. It's not illegal to do that. It doesn't change the liability under the law. So I really think they're—

Leslie Harris – Center for Democracy & Technology – President & CEO
All right, I think I understand now.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
If we think about the rules of the road for exchange, there are some rules that are prescribed by law under HIPAA and other legislation.   The first thing is to say, okay, where are the gaps? So when the DURSA process, they identified gaps and those were carried out under contract. Before DURSA other exchange occurred with contracts on a point to point basis. The purpose of DURSA was to consolidate all those multiple contracts. The question that we're asking is, are there additional gaps that aren't well addressed by contracts for which there should be a governance mechanism? Are we comfortable with that's what we mean and then we can put the language there?

Okay, 2.2, coordinated enforcement. Should there be a coordinated enforcement strategy that addresses these types of issues? I'm going to wonder why that's not under category four.

W
I think you're right.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Does anybody want to keep it here?

W
No.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Okay, 2.3, common elements and guidance. Should there be any common elements in these frameworks, guidance or templates? I'm sorry, which guidance, which—?

W
Where's the antecedent for—?

W
Oh, I think the thought there was in lieu, and this again may or may not be a governance issue as much as an item of feedback from the hearing, was if there isn't a single contractual agreement for the Nationwide Health Information Network that there was a suggestion that there be guidance or common elements or other work products, things that were put forward to address, as tools to address other gaps. So it probably may or may not be.

M
Would it be clearer if you used, under 2.1, as an example, frameworks, guidance or templates, so that people understand the relationship between 2.1 and the following?

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
For example?

M
Yes.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Sure.

W
Okay, that may be a better—

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Does anybody disagree with that? Anybody still out there?

W
Yes we are.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Okay. I think we've eliminated 2.2 and 2.3, so that takes us down to 2.4. Is there a role for governance at a national level to eliminate those barriers in a clear and consistent framework? I think—

W
Maybe the same as 2.1, or is there a need for—

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Well, I think we can leave that one in.

W
Okay.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
My guess would be the answer's yes, but we probably ought to answer it—

W
Directly?

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Yes. Does anybody want to change 2.4?

M
No.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Okay, we're going to see how far we can get through three before we take a break. So, establish technical requirements for health information network to assure a minimum level of conformance to the technical requirements, accomplish interoperability and policy objectives for trust, including the defined security level of assurance for the health information network.

So the proposed governance function is that there's a need for governance mechanisms that define technical requirements and related implementation guidance to support policy and assure technical interoperability. These requirements could cover data content, data transmission, security, functionality, including authentication, identification, access audit integrity controls, and including specifying levels of conformance to promote interoperability. The rationale is that a designated set of technical requirements is essential for interoperability and to enable exchange of health information in a highly fragmented industry. So those four boxes, are there any comments on those?

Elliott Maxwell
It may make it clearer, in line with earlier comments, if the governance objective is to establish technical requirements for the network to establish interoperability and policy objectives and then enforcement after that, so a policy preceding enforcement. Because the first key issues were essentially setting the policy and then the next issues would be conformance with the policy.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director

Okay, so it would read to establish technical requirements to accomplish interoperability and policy objectives for trusts, including a defined security level of .... Okay?

Elliott Maxwell
Then add to assure a minimum level of conformance or something like that. So it encompasses both the setting of the policy and the compliance with it, unless you want to put that all in four.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Yes, I think otherwise it would be redundant with four. So let me read the governance objectives again, which is to establish technical requirements to accomplish interoperability and policy objectives for trusts, including a defined security level of assurance for the Nationwide Health Information Network. Does that work for people?

Okay, can we move on to 3.1, coordinating policy and technical governance, ... policy and technical governance mechanisms are cohesive. Any comments on that?

W
What is that? I'm not sure I'm understanding that one. Mariann, do you—?

Mariann Yeager – NHIN – Policy and Governance Lead
This was done, obviously, very quickly following our Friday afternoon call. I think this was as one of the specific elements of defining technical requirements was does there need to be some sort of governance mechanism to assure that the policy objectives are met and to assure that the existing governance mechanisms are in fact cohesive. So similar to the concept that there would be possibly a need for some coordinating function for policies for privacy and security and trust, that should there be a mechanism to assure consistency and a minimum level of consistency in the technical requirements as the governance function, is that something that should be reflected here?

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
It seems to me that this issue basically says is creating a space for us to make a recommendation on technical requirements, what it should do.

M
Wasn't that just simply the ... under the heading of mission statement, sort of a mission or something that would go up above?

Mary Jo Deering – ONC – Senior Policy Advisor
I was going to say because what we deleted is a different statement. If that's John Houston on the line, and John, you're still breaking up a little bit, so et me just see if I understand what you just said, is that the notion of ensuring consistency or cohesion between those setting technical requirements and those setting policies is ensured. Did I hear you say that that should be raised or elevated, or am I misinterpreting you?

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security
That really is the objective and I guess it's where you just put it. So I agree with where you put it. Sorry.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Yes, I think the issue is that given the construct of this document we don't have a way of saying we're going to make a recommendation about what's in that objective. There needs to be an overarching place for that recommendation and so maybe the key issue is some synopsis of what's above it.

W
Yes, I think we can do that.

Mary Jo Deering – ONC – Senior Policy Advisor

But again this just says that the only thing you're trying to make consistent and cohesive are the technical requirements. And again just to restate and what I thought I heard somebody saying, is the need for this type of cohesion to be mapped consistently and cohesively back to the policy setting apparatus, it needs to be bumped above any of these categories into an introductory section. In other words, you don't want to— I always interpreted this to say, as we've said all along, you don't want to stovepipe the policy and the technology functions. You want to make sure that there's some way that setting and implementing the technical requirements are in sync with setting and implementing the policy ....

M
Yes.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
... an objective?

Mary Jo Deering – ONC – Senior Policy Advisor
I don't read that. I read this currently—and you're quite right, it's an artifact of the construct of the document, that within this document in this section we only talk about the technical requirements.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
But are consistent and cohesive to accomplish interoperability and policy objectives?

Mary Jo Deering – ONC – Senior Policy Advisor
I don't see that saying consisting in cohesive with— Because you're only trying to accomplish the policy objectives and I'm actually trying to make with the policy apparatus, with the policy requirements. Maybe I'm saying too much. I was getting at the actual apparatus that would be executing—

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
I'm just squinting at the screen now, but what I hear in Mary Jo's statement is a concern that the technical requirements are subordinate to policy and—

Mary Jo Deering – ONC – Senior Policy Advisor
I didn't mean that, Wes. Let me jump in. I didn't mean the notion of subordination.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Okay, I didn't think you meant that it should be that way. I thought you meant that the document could be read that way. I think what I'm interested in seeing is clarity that the policy and standards are jointly cohesive as opposed to the standards faithfully implement the policy, which was established a priori. So what it says now, should there be a mechanism or a process to assure that policy and technical requirements are consistent and cohesive?

M
Yes, ...

Elliott Maxwell
It might be useful in the preamble language to talk about the relationship between policy and technical, because there have been unstated assumptions about the relationship but you can deal with that in the preamble.

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security
Can I suggest that maybe another way to approach this is for each one of these governance objectives we simply put all of them at the top of the document or at least describe them at the top of the document so that people understand what all of our objectives are.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
So I think what we have is for 3.1 should there be a mechanism process to assure that policy and technical requirements are consistent and cohesive? Then a recommendation would be how that would

be accomplished. Can we move on to 3.2, national level implementation planning. Is there a need for coordinated national level implementation planning to assure ongoing interoperability as requirements change, address through coordination mechanisms or address through guidance only? I wonder if we could just drop those two choices, because there could be a third choice too, so you could do it by mandate. Are we okay with that question?

Okay, 3.3—

Mariann Yeager – NHIN – Policy and Governance Lead
Is there a sense from the group that that would be necessary? There was a theme from the hearing that there would be a benefit of having some type of coordination or guidance but it wasn't really specific in this, specifically targeting or recommending that there be some coordinated type of implementation plan similar I think to the type of practice that's used for HIPAA implementation planning at a national level, through ... serving in that capacity and looking and setting issues around that.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
I think we—

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
Mariann, I think we're getting ahead of ourselves in solution finding in this one.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Because we can still say no.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
Right.

W
Are you ready to say no?

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Well, I think the fact that we have it there is saying that it's a valid consideration. Can we move on to 3.3, shared HIN resources, should there be a mechanism to deem certain resources technical resources, certificate authority registries, provider directories, etc., for use in the HIN? Any comments on that one?

Michael Matthews – MedVirginia – CEO
I guess the same point or question I had regarding the exchange rates relative to the NTC and where does the NTC sit on this discussion or are we going to acknowledge NTC's work and leadership in this area at some later phase of our planning process.

Mary Jo Deering – ONC – Senior Policy Advisor
I've got a couple of observations here. The first is that again I know that there's separate work going on around provider directories, etc., and I think that there's other sub-groups that are looking at some of these issues. So it may well emerge that there's a specific recommendation to the policy committee through other channels that there be x, y or z, and that work is done then to create them. So this would say should we deem them.

As far as specifically acknowledging the technical committee, I think that, and I would also turn to Steve in this, that to the extent that there could be some specific technical activities that emerge through rule making, whether it's deeming this, then this would be something that almost falls under applicable law, I think. It would be a task that the technical committee no longer needed to perform because it could still be performed there but it could be that if there is something that emerges to perform some of these specific functions that it is no longer a need for the technical committee. But there was no intention to not respect the work done to date, it's just a question of where some of these might reside in the future and they might come up through different channels.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
So we've included there, for example, the ETC currently saves in this capacity for the exchange. Is there a similar mechanism needed more broadly for the HIN. Any other comments on 3.3?

Okay, 3.4, focus on core elements—

Mary Jo Deering – ONC – Senior Policy Advisor
Are you going to make a recommendation?

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
No.

Mary Jo Deering – ONC – Senior Policy Advisor
So anything that's in there is a yes?

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Well, I think anything that's in there is a— I don't think we would put a question in there if we didn't think the answer was there should be a recommendation.

Mary Jo Deering – ONC – Senior Policy Advisor
I wanted the record to show it.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
We're changing the rules a little bit—

Mary Jo Deering – ONC – Senior Policy Advisor
Okay.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
... two-thirds of the way through.

Mary Jo Deering – ONC – Senior Policy Advisor
Okay.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Okay, focus on core elements, consider governance of core elements to avoid fragmentation, but allow for innovation in other areas. So this would be actually governance would determine what those core elements were. Identify the core elements. So governance identifies the core elements and allows for innovation in other areas. So it would be governance would identify core elements and specify stuff, I don't know the exact word for that, how to implement.

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security
I'm just wondering whether, under the HIPAA security rules there are what they call required and addressable elements, and I'm wondering whether that same type of model is what we're really talking about here as well, or am I getting too far into the weeds with that suggestion?

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
No, actually I'm just wondering if this is an independent section, because isn't this one of our principles, is that we should—well, we should support innovation but we should do only what needs to be done.

M
You're right.

Laura Adams – Rhode Island Quality Institute – President & CEO
I agree.

Elliott Maxwell
Not wanting to stand between the group and lunch, but suggested by 3.2 and the notion of ongoing evolution there isn't anything now in the principles that talks about the ability of a governance functions to evaluate themselves and to evolve as the requirements evolve. It may be useful to think about that as a characteristic of governance that you might want to call out.

Laura Adams – Rhode Island Quality Institute – President & CEO
It was actually in the slides as one of the—I think it was the last bullet in the last slide under allowing for innovation, where it said it should be learning, it should have its own learning function built in.

M
... the slides, but I was looking at that and looking at the principles and we didn't capture that in the principles and it may be useful.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
So a candidate ninth principle would be learning, so to be the counter to devolution would be evolution, although they're not really antonyms, are they? Learning and the governance mechanism should—

W
...

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Yes. Actually, to have parallel construction, evaluation and learning. Does that resonate with folks?

Laura Adams – Rhode Island Quality Institute – President & CEO
It does resonate. I was thinking along the lines of the notion of continual improvement, but I'm assuming that that's assumed under learning.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
How about evaluation, learning and continuous improvement?

Laura Adams – Rhode Island Quality Institute – President & CEO
I'd like to see it in there, because I think we can learn a lot ....

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Yes, you can learn the same things over and over again.

W
It's unlimited.

M
But you do recognize I'm faster.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Yes. Well that might be a good note to take our lunch break.

Laura Adams – Rhode Island Quality Institute – President & CEO
I apologize for not being able to participate as fully today. I could not get a good Internet connection so I kept losing my ability to see the slides. I know we had them in other formats. I'm also not able to join this afternoon. But I'm really impressed with the work going on with this group and it's a pleasure to work with all of you.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Thank you. We enjoy having you here.

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security

I'm going to have to cut away part of the afternoon, too and will be away from the Internet. Are we going to continue on with this document and what else do we—?

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
I think what we have left to do is four and five.

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security
Are we going to work on any other documents that I need to print out before I'm away from the Internet?

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
I think after we do four and five we're going to take public comment and adjourn.

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security
Excellent.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
So we're well on schedule, maybe even a little bit ahead. We'll reconvene at 1:00.

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security
Great. Thank you.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Thanks.

(Lunch break.)

Judy Sparrow – Office of the National Coordinator – Executive Director
Good afternoon, everybody, and welcome back to the Governance Workgroup. We're ready to resume the meeting and I'll turn it over to Dr. Lumpkin.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Good afternoon. Welcome back. We have in front of us two remaining categories. We've gone through category one, ensure privacy and policies for privacy and security. We've gone through category two, which is the other policies and practices, category three, which are the technical requirements.

Category four, which is compliance, accountability and enforcement: Here the governance objective is to assure that there are designated, authoritative and trusted mechanisms to validate the conditions for trust and interoperability, to enable nationwide exchange are met, assure accountability and enforce appropriately. The proposed governance functions would be governance and mechanisms to assure compliance, accountability and enforcement, including validation and conditions for trust and interoperability are met and measures are in place to assure clear accountability and appropriate enforcement. The rationale for this is that validating compliance provides assurances that conditions for interoperability and trust are met, measures to assure ongoing compliance and that parties are appropriately accountable to reinforce trust in the health information network.

Any questions or comments on this component before we get into the individual sections? Okay. Hearing none, the first item is scope. How far down in an organization does governance reach? This is sounding familiar. I think we can take this one out because we covered that under the other section on nodes. Anyone disagree with that? Okay.

The second item is accountability of validation bodies. Should the health information network governance put forward expectations for governance of a certification/accreditation body, adherence to a set of governance principles? So this falls within the context of governance of governance. Any comments on this one?

W

I think the only clarification I would make is under the considerations options you've got the article a certification/accreditation body and I don't think we're trying to imply a singular entity.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Right.

Michael Matthews – MedVirginia – CEO
To clarify what we're doing at this point, are we developing an answer to this, a recommendation for it or identifying that it is something for us to have on our to-do list or to address subsequently?

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Well, we kind of worked out a little bit at the lunch break that that last column that says ―Recommendation" is probably a misnomer. What we're really talking about is what. So the question here is do we believe that there should be— We posed a question, but there is an implied answer in there and we just want to make sure that is, in fact, what we intend to imply. The question is should governance put forward expectations for governance and certification. The implication is that yes, by putting it there that we would have a recommendation on who should do that.

Michael Matthews – MedVirginia – CEO
From this morning's conversation I appreciate the line that you drew between ONC's suggestions for what's to be addressed versus the Workgroup's consideration of what's appropriate. I guess I'm still not at a point where I think that certification and/or accreditation is a given, that we're ready to start mapping it out. The form follows function. I still think that there's an ambiguity around all of the things that are to be governed and then what to look at. Are accreditation and certification the best tools of governance to be able to get us from here to there? So at this point, at least for myself, I'm not in a position of supporting a recommendation that we put forward expectations for governance of a certification/accreditation body, but I'd be interested in hearing others' views on that.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
How about if we were to make this conditional? So if certification and/or accreditation are employed should governance put forward expectations for these entities or should they just be free standing?

Michael Matthews – MedVirginia – CEO
I can certainly live with that condition.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
That begs the question of whether or not they should exist. I think we're going to need to have a fair bit of conversation about this, because the interesting thing on 4.2 is that the title of 4.2 is validation. Somewhere in this, if someone is going to play in the NHIN—or whatever it's going to be called—sandlot there has to be somebody to determine that they are the appropriate age and size to be there with the rest of the kids.

W
One of the things I would just also point out on the record is that, indeed, ONC has already completed rule making on certification and we are certifying not only full EHRs, but EHR modules, so that exists through rule making.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Maybe what we should do is further—maybe we could also just reframe it and say should governance put forward expectations for validation bodies. That makes it broader and then allows it to address with the certification for EHRs and modules, as well as whether or not there will be some validation entity, whether it's called accreditation for those who would participate in an exchange. That still will leave open the option of, one could think of it as a super DURSA, where enrollment in the NHIN would be based upon signing the document or essentially a super contract, which now is what happens with entities that are contractors or grantees of the federal government.

Michael Matthews – MedVirginia – CEO
I think that's a good point, John. That basically is my point. I hadn't thought about the certification of the validation body, but yes. That's another cut at it and until we get razor sharp on what's included and what's not included on languages that are so inclusive then, again, I just don't think we're going to have fulfilled our mission as a workgroup.

W
Just as a point of copy editing here, Mariann, I believe, if I understood John's edit correctly that top-line— not on 4.1—under 4.2, that if goes away and the sentence just begins should.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Yes. We kind of go back to almost the same structure it was before.

W
No. You take away should certification bodies exist. It just says should governance put forward expectations for validation bodies and the word certification ....

Elliott Maxwell
Is 4.1 then should there be conditions for participation and if so, how are they validated?

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
We don't ask that question anywhere else in the document. Elliott, I think that's a good recommendation.

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security
What happens if you have multiple bodies that are trying to act in this capacity? Is that something that should be supported or do we really want to have one—I shouldn't say one, but in any region or any one area do we want to have more than one body that can accredit?

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
So it's the highlander question? There can be only one?

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security
Yes or for any particular organization that needs to be certified or accredited can there only be one or can there be multiple? How does this all roll up, I guess?

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
I think then 4.1, I can say this, John or John Paul, the 4.1 we kind of got rid of initially because we had already addressed that issue in another item, but this would be is should there be conditions for participation in the health information network and then a sub-question of that; to 4.1 the sub-question would be then can more than one entity validate those conditions, that conditions for participation are met.

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security
I mean I think there needs to be certainty, but I also don't want to find that people go shopping for an accrediting body out of one is less demanding than another or there's some difference between the way that accreditation occurs.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
But that may tie directly into 4.2.

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security
Yes. That's sort of what I'm speaking to. Right.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director

So if the 4.1 is should there be conditions and then if there's more than one, but if those validation bodies are themselves validated through the governance process then the benefits of shopping should be less significant, but we could still say no. Okay. Anything else on 4.1 and 4.2?

Let's move on to 4.3, the brand. Should there be designated a mechanism to authorize the use of the NW-HIN brand? I think that's now actually 4.1, so I think we can probably move that up there.

W
Let me just think about this just a minute though. I believe that's correct, but bear with me. We have said that we have always assumed that there would be; I hate to use the word gradations of certification requirements, but again, based on access to sensitive information there will be a differing set of requirements put on anybody that touches that information or has access to that information. Is it; and I really ask this as a question; possible that if there is a certification process, an accrediting body to certify, that there might be some baseline certification that does not qualify for the brand, in other words, that the brand level is set at a higher level so that you can't just have two wheels or four wheels on your car; you also need a working brake system and shoulder strap and—

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Let me give an example. Let's suppose that I am a personal health record provider or I am hosting personal health records. It would seem to me that there has to be a mechanism for me to participate, even though I'm in the national health information infrastructure, so I can receive information that the individual has designated to come to me. But I wouldn't be part of the NHIN, so I wouldn't have the brand, because I wouldn't be part of the exchange. I'm only just a designated receiver of data. So that would be participation, but it wouldn't be branded.

Elliott Maxwell
Factually, is that a case that exists or as a recipient of data when you might be asked to send data to another party is it such that you would never be asked to provide data as a publisher?

John Mattison – Kaiser Permanente – Chief Medical Information Officer
I think that we have the question of that particular need ... for just use case, but my assumption base is that PHR vendors will be both, recipients and senders.

Jodi Daniel – ONC – Director Office of Policy & Research
I guess the question is are there possibly different levels of participation and different criteria or just different accreditation or something short of accreditation. Are there possibly different levels of participation and whoever we say that branding participation otherwise that we might want to consider?

Elliott Maxwell
We have sometimes used the analogy of the Energy Star appliances, but it may be useful to think of the environmental architecture rules that classify buildings according to gold, silver, platinum standards so there can be multiple standards that people can hold out and say they met these. It's just another analogy, so it's not just one. There can be multiple levels.

Michael Matthews – MedVirginia – CEO
I'm glad you made your point in that way as well, because a lot of what we discussed through the morning seemed to relate more to an exchange type of activity than it did an all-inclusive whatever we're calling it, NW-HIN. That would include direct and other things. So I think having different levels of participation would be in sync with that more inclusive scope, but we need to be thinking of something broader than exchange as well.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
So I'm trying to think about looking at the new language in number one. Should there be conditions for participation in the NW-HIN based upon type or circumstances of participation? I know I used participation twice in the same sentence, but we can wordsmith it later. So basically we're asking two

questions. Should there be consistent conditions of participation and can they vary depending upon how one participates?

Jodi Daniel – ONC – Director Office of Policy & Research
Also—you just deleted the last question here—but is it possible that you need to hit a baseline, but that people might hold themselves out as meeting the gold standard instead of just the base standard, that not necessarily based on what type of entity they are, but just based on what level of trust they're comfortable with.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
I think that that may be getting to a level of specificity that we don't need for governance.

Jodi Daniel – ONC – Director Office of Policy & Research
I'm just asking if that's too limiting, what you were saying, that it's based upon the type or circumstance of participation. Is it just different levels or do we need to specify why there might be different levels and only limiting it to the type—

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Well, the type may be just as a PHR vendor who is only sending and receiving directed data. It could be a national laboratory that would want to participate through the local health information exchanges without having to go through an agreement with every single one of the 100 different HIEs. There are many ways that you can think about national entities wanting to relate more to the HIN than they would to each individual HIE. That would be one type.

W
But would it be better, since I think that people are having difficulty with the wordsmithing and I have some difficulty labeling it by entity per se and to say should there be conditions for participation and if so, on what should they be based?

Jodi Daniel – ONC – Director Office of Policy & Research
Should there be different levels—?

W
Or should they allow for variation—

Jodi Daniel – ONC – Director Office of Policy & Research
Right.

W
Should they allow for variation and, if so, based on what?

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Sure.

W
That way I think we've got time to think through what it is.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Yes. Okay. Then we go from there to two—

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security
The idea of participation, now is that something that falls under this category or is that more of an over arching concept that needs to be addressed maybe outside the scope of this particular session?

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
I think you're right. It doesn't—

John Mattison – Kaiser Permanente – Chief Medical Information Officer
I think it would be a good off-line exercise to take a stab, not that it would be definitive or immutable, but a stab at the taxonomy of participants, senders only, receivers only, senders and receivers, various entity types and use that as a reference document for several of the discussions, which might source by that same taxonomy.

W
Again, I know the Tiger Team has looked at it again, not, as I said at the beginning, so late on the basis of their access to sensitive information as opposed to who they are and which direction the information is flowing. So I think that we'd want to keep it simple and determine what are the truly distinguishing differences that make a difference.

John Mattison – Kaiser Permanente – Chief Medical Information Officer
I completely agree.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Can we go back to two? What's left in two? Yes. I wanted to see point two. Okay. Keep on going. I'm just wondering if maybe what we should do is take two, replace two, so reverse the order and have two actually be general considerations. Then we can work with all of the other ones, but that would be where we talk about participation. I think we'd have to look through all of the other recommendations, but I have the feeling there are a couple of issues that probably would fit better in a general category than under privacy or so forth.

Elliott Maxwell
Is this participation question a first order question?

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Yes.

Elliott Maxwell
So it may be even before you get to the privacy and security—

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
I think there are a series of first order questions. How far into the nodes should we get? I think that's a first order question. We think the principle there is to do the least amount of harm possible kind of thing. It just seems to me if we go over this there will be two or three items that would be first order.

W
I want to question that. I had assumed we were not making any priory assumptions about who could participate or why; that is was based on very specific things. In other words, we weren't going to say a priory X type of entity cannot ever exchange health information because it's not enforceable. Just another editorial point, we had worked very hard to get the word participation out of most of our documents because it has an image to it that is certainly ... exchange, but it connotes a type of environment that is probably certainly not the totality of what's going to exist.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
But I don't know that we can have a section on accountability and enforcement, which talks about one of the mechanisms being exclusion without saying how people get in.

Jodi Daniel – ONC – Director Office of Policy & Research
But shouldn't be other types of enforcement that aren't limited to exclusion? I mean you have government oversight and enforcement without having an exclusion from participation or—

W
How they get in is based on sections one, two and three—?

Jodi Daniel – ONC – Director Office of Policy & Research
... participation that you're raising?

W
It probably only is legacy. Primarily it's legacy and then it sounds like, number one, there's an it. There is a club. You're going to join. We certainly stripped out join. Participate was a little better. We've kept it and strictly speaking it's fine, but again, it has an image of exclusion or something and to the extent that there was any exclusion it was going to be because of very specific things that were not happening or criteria that were not met.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Yes, except that the issue of there is an it is implicit in the charge to this committee. I mean we're—

W
... the definition—

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
But it's if you are going to have governance then there are people who are governed. We got here because the DURSA, which was an initial phase, only applied to those who had a federal contract or a grant or were a federal entity. At some point we want others to be able to; I can't think of a better word than participate in this thing. So how do we do that?

Christine Bechtel – National Partnership for Women & Families – VP
I would ask that in your potential scope of the governance rule the second bullet is potential leverage for participation, because some of the enforcement mechanisms are if you don't get federal funds you can't receive federal data. So I think I'm more okay with the concept of participation in that regard.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
How about if we, rather than argue this out right at the moment, replace the word participation with exchange through the NHIN?

W
Yes.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
And that we can go back to 4.1. Okay. So should there be conditions for exchanging health information through the NHIN? So instead of conditions of participation—

W
... participation ... exchanging information—

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Through the NHIN and the NW-HIN. Whatever. I hope you guys pick a name soon, because I'm going to start calling it the NHII and just go back.

W
We can call it John.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
There are too many people who want to go to the John anyway. Okay. So we're going to move. We're going to go through and pick some of these items that probably ought to move into a first order question. Who has the right to exchange health information through the nationwide health information network? Okay? Then we go through privacy and then we go through the particular pieces that will fit in there.

I think that brings us back to 4.3, which I think we need guidance from ONC on, because if you're not participating can you put on your letterhead that you're authorized to exchange information through the NHIN. Well—

W
... sending data—

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Well, I'm trying to figure out if we need to get guidance on the issue of do we select people to participate versus we just say that they exchange and the if they do exchange who gets to use that as a brand?

W
Here's one way that I would parse 4.1 and 4.3: In my mind, 4.1 gets us back a little bit to this notion of core or foundational whatevers, criteria. Are there some criteria for exchanging information that are considered absolutely core, absolutely foundational to any time you are going to touch any kind, whether it's aggregated, whether it's de-identified? Is there something that goes across everything? That might or might not reach down deep inside a node or it might stop somewhere.

But then you've got the new name, which represents a particular level of practices for privacy and security and interoperability, which are deemed robust enough for the government or some certifying or accrediting entity. This is hypothetical, because we may not go down this path, but I'm just playing out the scenario for them to actually be an accredited new name, Energy Star Level Four or whatever it is exchanger of information. So those are sort of the scenarios that drive these questions.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Okay. So it's that's the governance issue, who should be able to use the brand? So should there be governance structures to determine who should be able to use the brand? By having that question there we're presuming that we should make a recommendation on that.

W
The question ... almost goes up in 4.1 perhaps ... core, foundational—

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Yes. That's a sub question of variation.

W
Can I ask a question on 4.1? We say can more than one entity validate the conditions for participation are met. It seems to me you can do this two ways. You either have the certification/accreditation approach where you have an entity validating the conditions of participation are met or you could have a brand approach where somebody can assert that they have met the conditions of participation unless it's shown that they haven't. I mean you can. It's making an assumption and I—

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Yes and that assumption actually should be a subset of 4.2. So if we decide that there should be validation bodies— Should there be more than one entity that validates? We need to go through and change all of the conditions of participation or conditions for exchange of information through the new name. Okay.

Let's go on to 4.4 then. Should there be accountability measures for operations and management to share technical resources or services for the new name? What does that mean?

W
Mariann, why don't you explain that? Yes.

Mariann Yeager – NHIN – Policy and Governance Lead

If there are resources that are identified for use by the NHIN or NW-HIN, whatever you want to call it, such as provider directories or certificate authority services, should there be some accountability mechanisms to make sure that the shared services are appropriately operated and managed if there are, in fact, other parties to the HIN that are relying upon them? In other words, it's oversight of these shared services or whatever is necessary, if there's a dependency on others to use them.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
So, in 4.1 we talk about conditions for exchange. In 4.3 we're really talking about the infrastructure of the new name. So we're saying should there be a validation process for infrastructure necessary to facilitate exchange through the new name.

Mariann Yeager – NHIN – Policy and Governance Lead
And should there be some oversight and assurance that it's operated and managed in an effective way for reliability and continuity, particularly if it's necessary to support production level information exchange.

Elliott Maxwell
The context of the question is if one said that to hold yourself out as meeting some kind of standard and that involves secure routing or identity proofing or some other element and they were either self provided or by intermediaries is there a need for a mechanism to say yes, in fact, the party that posed themselves out in this way is actually performing these services?

W
I think it's, if I understand it, one very clear example is let's stick with provider directories, because right now we don't know. We're waiting for a recommendation whether we'll let the states create state provider directories and then try and harmonize them because the states are closest to the providers or whether, failing that, we'll just get a contract and contract somebody to create a national provider directory looking at the current ones for Medicare, etc. and come up with a facilitated provider directory that everybody is going to use, so whatever it is you've got something that everybody is supposed to be using. How do you or should you oversee that whoever is responsible for keeping those provider directories up to date is really doing it since everybody has to use those directories as a condition of exchanging information?

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
So we're really talking about non-federal assets.

W
It could be. It could well be a non-federal asset.

W
It could be.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Because if you contract with someone to do a national provider directory that becomes a federal asset and so the governance structure is the contract. If states contract with someone to set up a state one then there needs to be some mechanism to ensure that they're doing it in a way that will enable exchange.

W
Yes.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Okay. So we can leave that the way it is then?

Elliott Maxwell
Maybe an example would help the reader, so using provider directories ... provider directories or some other example.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Anything else on 4.4? Probably each state or non-federal provider directories.

Should there be a mechanism, going on to 4.5, to verify ongoing compliance or repercussions of non-compliance? Yes?

M
By all means.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
4.6: Coordinated enforcement. I'm just thinking of what the opposite of that is. Should there be a coordinated enforcement of policies regarding compliance with new name policies and technical requirements for trust across existing authorities, states, FTC, OCR, etc.?

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security
Obviously, I agree with this. I'm looking through the next couple in order and I'm wondering what the order of 4.5, 4.6, 4.8 maybe need to be, maybe 4.9, because I guess I sort of logically look at sort of a sequence here of things that happened. Obviously, if there's a complaint or there is some other knowledge that somebody is not appropriately performing to whatever standard, that there has to be enforcement, but should we sort of put this in some type of logical order just to make it easier to follow?

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Compliance—

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security
I'm thinking like complaints and enforcement, ongoing compliance or maybe it's complaint enforcement, coordination of breach notification, alternative dispute resolution, ongoing compliance or actually, maybe remedies and sanctions and then ongoing compliance.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Well, I think I'm comfortable. I agree that there should be a logical order. I'm comfortable with ongoing compliance being first, because I think if I'm a citizen or any other person living in this country whose information is going through these things I kind of want to know that I don't have to complain for things to be right. Then, after that, I want to know that if I do make a complaint that it would be handled appropriately.

W
And some of these things won't be citizen complaints. I mean ongoing compliance, I'm voting with John here, because there's the notion that some of these are technical things deep down buried that the citizen is never going to complain about, but boy, if you're actually changing information on the other hand you really want to know that, indeed, stuff is going right.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
So then we have ongoing compliance, complaint, coordinated breach notification—

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security
Well, coordinated enforcement and then breach notification.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Okay ... with that.

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security
Breach notification would be once you figured out there is actually something that has happened. Maybe it's investigation and enforcement, because investigation really is a part of this whole string.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director

I'm thinking part of this construct of this document puts us in a little bit of a bind and I'm just wondering. All of these shoulds should be what should. What should be the mechanism to address complaints?

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security
You're right.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
What should be the mechanism—?

W
To verify ongoing compliance—

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security
Right because we're essentially trying to say should there be and then we're going to answer our question when, by including it, we've already made the decision it should be there.

W
But the reason that we put should is that you had the option here to strip something out and say, ~~No~~, I don't think that should be part of it."

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security
But I think that's what we're doing right now is stripping out those—

W
Exactly. So instead of saying yes you just change the ... the question.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
I wouldn't worry about it. We can do that.

W
... .

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
So we have complaints, address complaints; coordinate investment; coordinate breach notification; ADR and redress.

M
Yes.

Jodi Daniel – ONC – Director Office of Policy & Research
On 4.7 we have coordinate investigation enforcement and all of the examples are just governmental enforcement. Is that intentional?

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
No.

Jodi Daniel – ONC – Director Office of Policy & Research
Okay. Because I know it's examples, but they're all—

W
I was going to say instead of etc. you could say and non-governmental authorities.

Jodi Daniel – ONC – Director Office of Policy & Research
Of course, that poses the challenge of facilitating enforcement when you're talking about different types of authorities. I mean, it's one thing to say FTC and OCR should coordinate their efforts and that's a doable thing and has been done with privacy violations, but coordinating enforcement we're talking about private

actors and governmental actors and state versus federal is quite challenging, a laudable goal, but I'm not sure how one would do that successfully.

M
Maybe that should be in the form of a question. Is there a good mechanism—

Jodi Daniel – ONC – Director Office of Policy & Research
That will get it. Mariann, just re-write that. What should be the mechanism?

Michael Matthews – MedVirginia – CEO
To add to is there the regulatory authority to be able to coordinate enforcement?

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Actually, what is.

Mariann Yeager – NHIN – Policy and Governance Lead
Is that okay? Did I get the order right?

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
So we've got ongoing compliance; complaints; coordinated investigation and enforcement; coordinate breach; ADR; re-dress remedies and sanctions. Are we okay with these? 5.0: Oversight of governance mechanisms to determine how governance processes are performing and adjusting to new circumstances. This is consistent with our new principle, so that's good.

To determine, propose the governance function's oversight of the new name governance mechanisms is necessary to assure effective governance. The rationale is oversight; that sounds redundant; oversight is necessary to assure governance objectives are met and assure governance mechanisms are effective and able to adapt over time.

Monitoring: What should be the reporting or monitoring of new name governance mechanisms and how deep should the monitoring go or how granular? What are the measures?

W
I think there's a difference between what are the measures and to whom they're applied, right?

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
What are the measures and to whom are they applied?

Michael Matthews – MedVirginia – CEO
Help me understand this one. I think I was on a different wavelet when this one was talked about before. When we started out with policies, mechanisms and oversight I thought it was oversight of the policies and the mechanisms, but this sounds like this is oversight of governance.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
That's correct. We adopted a new principle right before we broke for lunch that said that evaluation, learning and continuous improvement, so this is how we assure that the governance process helps foster, promote innovation, because it's looking at how it's functioning and what its impact is upon the system of exchange of health information. So my interpretation of 5.0; this is how it evaluates and learns; the governance process itself is evaluated and learns from it.

Michael Matthews – MedVirginia – CEO
Does that imply that the governance authority cannot do that work itself, it has to be done by some entity external to the governing authority?

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
I wouldn't say that.

Michael Matthews – MedVirginia – CEO
Okay.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Then we'd have to create a whole new governance body to oversee the governance body. Okay. With that, anything else on 5.1? 5.2: What should the governance mechanism for reporting to track issues, complaints and disputes relative to the new name? 5.3: What should be the oversight of ongoing compliance efforts? There are a couple of options that are there, but there may be others. Then 5.4: If there are multiple governance entities how should they be coordinated? How should oversight be coordinated or something like that?

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security
I'm almost thinking that 5.4 needs to be moved up. I just think it needs to be given more attention rather than the last thing on the list in the whole document.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Anybody opposed to moving it up to number one?

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security
I guess they're all very important concepts. This seems to me sort of almost the heart of a lot of what we need to think about and worry about.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Yes. I think, actually, I'm going to argue for not even being in 5.1 and we move it to section, the new section one, which is on the over arching issues.

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security
Yes. I just think this is incredibly important from my perspective.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Right. It's not even in monitoring ongoing; it really is a component. Anything else on section 5.0?

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security
No, not from me.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Any over arching comments?

Mary Jo Deering – ONC – Senior Policy Advisor
I'd just like to share a thought. I propose nothing specific here, but it gets to the notion of protecting several notions, but above all, protection against harms. It first occurred to me several, many meetings back, months back when there was always emphasis on innovation and above all, don't stifle innovation. I never heard anyone elevate as strongly that we actually can anticipate some known risk. We know what some bad things are.

Do we have a way of adding a final filter when we're done and we've looked at all of our governance things that we've put in place that says can we check off the things that might be most afraid of? I once said we should ... the NHIN. I mean really, do a worst case scenario, the things that you can ... and just as a means of validating, that you haven't overlooked something, because this is new. It's big. It's complicated. The principle that you'll be validating against is am I pretty sure that a harmful scenario that I can anticipate is somehow covered here? I think we've done the job, but I've never heard it as a conscious check. We just talk about privacy and trust and security almost from the abstract framework point of view as opposed to –

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director

So could we build that into 5.2 on reporting? So if there's a regular reporting there is some assessment of protection against risks versus promoting innovation and some description and discussion of that as part of the report?

Mariann Yeager – NHIN – Policy and Governance Lead
Are you talking, Mary Jo, about the concept of risk management and John, your point of assessing the risks, but also making sure that governance has a mechanism to try to manage those risks and evaluate the risks?

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
So it would seem to me that there are—I probably haven't done this for a while, but it would seem to me that there are two types of risks. There are known risks and there are unknown risks. You do war gaming or scenario planning to identify, to make the unknown risks known and then you balance those known risks for/against the benefit, one of the benefits being that people have the right information, they need to make the right decisions at the right time. Another benefit is that there is innovation in the process of exchange. Just having health information recorded electronically or on paper somewhere is a risk. There is that benefit that you can retrieve it at some later time.

This would suggest that we would be expecting the new name to do two things in the governance of the new name in that annual report; to identify as many unknown risks and to make some assessment of the risks that are in the system versus the benefits that accrue from having that level of risk.

Leslie Harris – Center for Democracy & Technology – President & CEO
Are you talking about doing some kind of risk/benefit analysis that is shared among the participants or that's put out publicly? I mean risk assessment and risk management ought to be something that each node or participating entity engages in.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
I would think, since one of our principles is transparency, that would be shared publicly. I mean we wouldn't talk about the various back doors in the system as part of that risk assessment, but—

Leslie Harris – Center for Democracy & Technology – President & CEO
That's what I was wondering.

Elliott Maxwell
It's also in the analogy of the financial system, looking at a systemic risk as opposed to any individual node or any individual practice.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Yes. Does that give you some comfort, Leslie, or discomfort?

Leslie Harris – Center for Democracy & Technology – President & CEO
No. It does. I just also don't want to relieve participants from what I just consider accountable practices, which is risk management. I just want to make sure we're not saying that all of that work happens at the top.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Yes. After you said that I'm trying to think of where we do that. I'm just going to suggest maybe that's a policy that we want to have governance affect, although we're not going to get down into the weeds of which policies those are.

Leslie Harris – Center for Democracy & Technology – President & CEO
Right. Okay.

W
... then in the new preamble ... that ...? Where would we put it?

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
I don't think we put it here.

W
Okay ... policy statement.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Well, it's how we can tell governance is working is whether or not governance has addressed that issue.

Elliott Maxwell
The notion of devolution is the idea that, in fact, we drive it down to people, who are most directly affected and they should be making these decisions based on a risk/benefit analysis closest to where it's happening.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Right.

Elliott Maxwell
I have one other question and that is we have circled in the past around the question as to whether the working group would make recommendations about policies, privacy and security and the like that may apply not only to people who are exchanging information under the purview of whatever the new name is, but all exchanges of health information, what Mary Jo, I think, was referring to as the sort of core protections that may go beyond existing law. I don't think we've tracked that anywhere in this framework now or I haven't been able to find it and if so, does the workgroup want to address that?

W
... or was it ...?

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
No. I think the scope of our work is exchange through the new name and governance related to that. So if my doc has a brother, who has a similar specialty in another city and they want to send stuff back and forth, but not do it through the exchange, I don't think that was our scope.

Elliott Maxwell
If the brothers exchanged data by the NHIN Direct I thought that was within the scope.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Yes. So that would be different than if they just sent it through e-mail back and forth; where we're talking about the governance applies to anything that goes through the nationwide health information network. We've already said that we will look at governance mechanisms that would have different levels of use of the national health information network to exchange health information.

Elliott Maxwell
Maybe I misunderstood. What I thought I heard was if the brothers were not using exchange.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
If they were not using the national health information—I may have said that, but not really meant it if they're not using the nationwide health information network.

Elliott
Thank you for the clarification.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director

Do we have any other general comments, things we might have missed, things, gaps that we haven't done as part of our gaps analysis? Okay.   We have completed our task except for one thing, which is to listen to public comment.

Judy Sparrow – Office of the National Coordinator – Executive Director
It is the time for any public comment. Please state your name, your organization and there is a three-minute time limit. Operator, are there any public comments?

Operator
No, Ms. Sparrow, there are no calls.

Judy Sparrow – Office of the National Coordinator – Executive Director
Well, thank you very much. Thank you, Dr. Lumpkin and members of the workgroup.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Thank you, all. Have a good week.

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Great work to all of the staff that supported these documents and facilitated this and, John, great facilitation. Thank you very much.